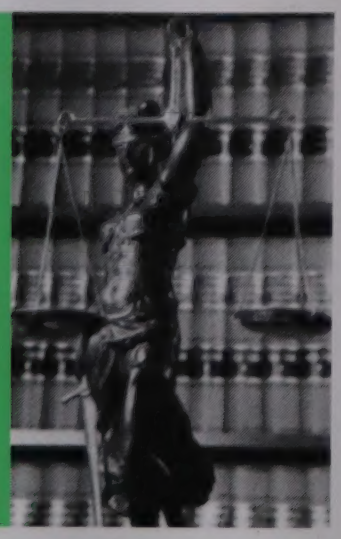
REPORT OF THE FOURTH PEOPLES' COMMISSION ON REVIEW OF LEGISLATIONS AMENDING PATENTS ACT 1970



OCTOBER, 2004

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Former Prime Minister of India

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Senior Advocate,
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Convenor

Shri B.K. Keayla
Former Commissioner of
Payments Government of India

Commissioned by
National Working Group on Patent Laws
and
Public Interest Legal Support & Research Centre
New Delhi, India

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National Working Group on Patent Laws and Public Interest Legal Support and Research Centre (new Delhi based non-official organizations) constituted Peoples' Commission on Review of Legislations amending Patents Act 1970. The Report of the Commission is presented to the people of India hoping that Parliament and Government will consider the views expressed in the Report.

- First Peoples' Commission Report on GATT - 1996
- Second Peoples' Commission Report on Intellectual Property Rights - 1998
- Third Peoples' Commission Report on Patent Laws for India - 2003
- Fourth Peoples' Commission Report on Review of Legislations Amending Patents Act 1970 (October 2004)

Where the mind is without fear
and the head is held high;
where knowledge is free;
Where the world has not been broken up
into fragments by narrow domestic walls;
Where the words come out from the depth of truth;
Where tireless striving stretches into arms
towards perfection;
Where the clear stream of reason
has not lost its way into the dreary desert sand
of dead habit;
Where the mind is lad forward
by theee into ever widening thought and action
into that heaven of freedom,
my Father, let my country awake.

-Rabindranath Tagore

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Preface

The criticality of the TRIPS Agreement for our country was understood by me when as the Chairman of the Standing Committee of Parliament of Ministry of Commerce, the committee examined the Draft Dunkel proposal relating to Uruguay Round of GATT Negotiations. Even at that time that Committee had opined inter-alia that India should insists for grant of automatic licences in certain circumstances, and that micro-organism and bio-logical processes should be kept out of patent regime. The impact of the product patent regime on the drug prices was also pointed out. The concerns are still important for our country.

In January 2003 the Peoples' Commission on Patent Laws for India of which I was the Chairman along with other senior experts as Members submitted a comprehensive Report after taking evidence of a large number of senior scientists, legal experts and representatives of the industry. A number of serious re-commendations were made on the patent laws and policies for our country within the framework of the TRIPS Agreement.

The government introduced the final Patents (Amendment) Bill in Lok Sabha in December 2003. The experts of the National Working Group on Patent Laws and Public Interest Legal Support & Research Centre made a preliminary examination of the Bill 2003 and the earlier amending enactments of 1999 and 2002 and briefed me that several important issues relevant to the patent system have been ignored in the amending process of the Patents Act 1970. The seriousness of the issues were considered in-depth on the suggestion of both the groups and other eminent persons and I agreed to the constituting of another Peoples' Commission to Review the patent legislations amending the Patents Act 1970.

I agreed to be the Chairman of this Commission. A few other eminent persons also agreed to be the member of the Commission to sit, discuss and consider with an open mind the crucial issues involved relating to the patent laws for our country. The Press Release issue on February 3, 2004 establishing the Fourth Peoples' Commission may be seen at Annexure I. The re-commendations of the Commission are two parts. The important and core issues requiring amendments have been tabulated in Appendix I. While the other amendments needed have been listed in Appendix II.

The re-commendations are based on the clarifications and flexibilities unambiguously stated in the Doha Declaration on TRIPS Agreement and Public Health. The re-commendations keep in view the findings of certain important international studies in TRIPS Agreement published in the recent past and the issues raised by important Members of Parliament during debate on Patents (Second Amendment) Bill 2002. The Constitutional obligations and the goals and objectives contained in the National Health Policy and the National Pharmaceutical Policy have also been kept in view. The Report is submitted to the government, Parliament

and to the people of our country for upholding the safeguard measures necessary to protect the health and well-being of our people.

I thank the Members of the Commission for sparing their valuable time for taking keen interest in the deliberations of the Commission and for producing a well-considered Report. On behalf of the Commission, I place on record our appreciation of the extensive contribution and assistance by Mr. B.K. Keayla in finalizing our Report.

(I.K. GUJRAL)

New Delhi

October 19, 2004

INTRODUCTION AND OVERVIEW

1. Any regime of intellectual property rights has to deal, at a conceptual level, with two basic contradictions. First, any scientific invention is founded upon pre-existing knowledge which is a common heritage, the common property of all; likewise any scientific invention must also contribute directly to this common pool of mankind's knowledge. The boundaries between this *common* property and what could constitute *private* intellectual property have to be drawn in any intellectual property regime; it is however conceptually difficult to do so. An intellectual property regime must be careful, for instance, not to allow the private appropriation of hitherto-unappropriated common knowledge (such as patenting of *basmati* rice); nor should it allow the private appropriation of the knowledge of something *which already exists*, a knowledge that properly belongs to the common domain, as distinct from something which is *developed* by the patentee. (This is the argument for not permitting the patenting of living organisms).Secondly, an intellectual property regime necessarily sets up a monopoly, which it justifies on the grounds that certain inventions of benefit to mankind would never occur without such monopoly rights. All monopoly however entails a squeeze on the people through exorbitant pricing. How much monopoly rights should be granted, what is the point at which the beneficial effects of monopoly rights cease to operate and monopoly becomes baneful for the people, are matters which an intellectual property regime has to decide on, but which again are intrinsically difficult.

2. While the foregoing considerations are relevant for any IPR regime, they acquire particular urgency when the regime is a "global" one with which all individual nations must comply, and in accordance with which all nation-States must amend their patent laws. The exorbitant pricing owing to the monopoly rights conferred by the IPR regime then has the additional dimension of a squeeze on the third world population by the first world MNCs. The conferring of monopoly rights over intellectual output then has the additional dimension of refurbishing the technological dualism in the world economy, of ensuring that the third world economies, even the large ones among them which are capable of doing otherwise, remain technologically dependent on the first world. Likewise, the specification of the boundary between the common and the privately patentable knowledge acquires an additional importance in so far as the hitherto commonly shared bio-diversity of the third world becomes vulnerable to private appropriation by first world monopolists. In short, in addition to the *general* problems associated with any IPR regime, the whole array of problems of dependency and hegemony in the world economy come to the fore when we talk of a "global" IPR regime. Or putting the matter differently, any IPR regime which a *nation* like ours adopts for itself even as it gets enmeshed in a network of "global" relationships, has to be sensitive not only to the problem of private appropriation of common property, and to the problem of monopolistic exploitation through exorbitant

pricing, but also to the issue of hegemony and dependency in the world economy through the technological monopoly enjoyed by the advanced world.

3. The 1970 Patents Act, adopted after years of deliberations, was a remarkable piece of legislation precisely because it showed these sensitivities in abundant measure, and was hailed as a model Act not only in other third world countries but among progressive intellectuals in the first world itself. With its denial of product patents in certain sensitive sectors of economy, its provisions for compulsory licensing, its fixing of the patent term at seven years for three particular sectors, and a host of other measures, it succeeded to a great extent in providing a balance between the presumed need for some monopoly rights for ushering in inventions, and the interests of the people, including the need to overcome technological dependency. It is sometimes argued that the niggardly provision of monopoly patent protection by the 1970 Act discouraged *domestic* research and inventiveness, but this argument is untenable. The fact that the overwhelming bulk of patent applications under the regime set up by this Act came from MNC off-shoots in India (some came from the public sector) rather than from the Indian private sector, suggests that it is neither the patent regime *per se*, nor even the sheer fact of import restrictions (the other reason often adduced for lack of inventiveness), that was responsible for the meagerness of research among domestic producers generally, and private producers in particular. More fundamental structural factors were obviously at work. In this situation, where a basic difference in research and inventiveness between the advanced countries and India *was a fact of life,* it was necessary to have a patent regime that minimized the monopoly gains of the MNCs even while making new technology accessible, rather than chased the chimera of domestic inventiveness by providing for stronger monopoly positions. And this is precisely what the 1970 Act did.

4. It is not surprising that the demand for patent regimes in the third world that provided for *stronger* monopoly positions, came not from their domestic capitalists, but from the MNCs. A group of MNCs banded together, and worked relentlessly behind the scenes, first, to work out what they considered an "ideal" "Global" Patent regime, and then to "sell" it to the U.S. Administration, and then to have it put on the WTO Agenda through the courtesy of this Administration, and then to have it adopted as the TRIPS Agreement, in accordance with which all national Patents Acts had to be amended. The thrust of their whole effort was to *overturn* the 1970 Act in India and similar legislation elsewhere(e.g. Argentina, Brazil, South Korea) which had sought to whittle down their monopoly positions in the interests of the third world people. In short, the TRIPS Agreement was an endeavor, using the WTO forum, to re-impose

on the third world a regime of monopoly domination by the MNCs from which the third world countries had been trying to escape, through the enactment of suitable legislation by their respective States. The TRIPS Agreement did not represent some sort of an "ideal" or "optimum" regime. It represented nothing intrinsically sacrosanct, only an imposition reflecting, in the last analysis, the unequal bargaining strengths of the participants in the Uruguay Round Negotiations at the time.

5. Scarcely anybody in the country has argued that the TRIPS regime *per se* is good for India. The responses to it, as reflected in the divergent positions taken over the amendments to the 1970 Act, have been three-fold. First, there has been a conservative response which has argued that the country must honour its international commitments, and that having signed an Agreement which was the best we could get under the circumstances, we must now proceed to put it into effect through appropriate legislation. The second, and perhaps the most preponderant, response has been that even within the TRIPS Agreement there is some leeway, certain openings, such as references to national interests, professed concerns for the conditions of the people, which can be used even while amending our 1970 Act to make it TRIPS-compatible, to ensure that our government retains adequate legal discretion to intervene in the interests of the people. Clauses such as those relating to compulsory licensing which occur in the laws enacted in China and Brazil could be replicated with impunity in our Amendment of the 1970 Act. The third position has questioned whether in matters affecting millions of people the mere signing of an international agreement by the government of the day should make the agreement *ipso facto* binding on the country without an in-depth national debate and a specific legislative mandate arising out of such debate. This viewpoint is further reinforced by the fact that developing countries including our own have called for a review of some of the basic provisions of the TRIPS Agreement, as part of the implementation agenda of the ongoing Doha Round of Negotiations and that review is far from complete. While the three positions are quite distinct in their approach and emphasis, the second and the third tendencies are not mutually exclusive. The approach of successive Peoples' Commissions including ours, it is only fair to say, has striven to forge a feasible synthesis of the second and the third positions.

6. **The debate on what position to take is far from settled. The process of amending the 1970 Act is still on. Meanwhile however there have been certain positive developments in the international arena itself, in the form, above all, of the Doha Declaration on TRIPS Agreement and Public Health. The Declaration of the 4th Ministerial Conference at Doha in November 2001, stated: "..while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can**

and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular to promote access to medicines for all." It considerably increased the leeway available to national governments to use their discretion for protecting the people from the rigours and excesses of the TRIPS Agreement which had sought to strengthen the global monopoly position of the MNCs. The Doha Declaration, itself a reflection of the changing global environment, provides us with a niche of opportunity, before we complete the process of amending the 1970 Act, to retrieve lost ground to some extent. This chance alas has not yet been used either in the 2002 amendments or in the Draft Patents Amendment Bill 2003, both of which came after Doha. We urge that before the Draft Bill is made into law, it must be altered, taking advantage of the leeway that already existed and which has been somewhat increased by Doha, to protect the interests of the Indian people against the MNCs.

7. The details of where the proposed amendments should be altered, together with the justifications for asking for such alterations, have been given in the following chapters. But roughly they relate to the following main areas :

(i) *The first relates to patentable subject matter*. The term "invention" should be reserved for a "basic novel product or process involving an inventive step and capable of industrial application". All three criteria, "novelty", "inventive step" and the quality of being "capable of industrial application", must be insisted upon.

(ii) *The second relates to what is not patentable*. The proposed amendments allow patenting of " micro-organisms" and "non-biological and micro-biological processes". This must not happen. Micro-organisms, including viruses, should not be patented, and hence should also figure alongside plants and animals, including seeds, varieties and species, in the list of non-patentable items. Since the WTO itself is currently engaged in reviewing the issue of patenting of "micro-organisms "and "non-biological and micro-biological processes", we need not hasten to pre-judge the issue against our own interests by declaring them as patentable straightaway; there is no need to start crawling before we have even been asked to bend.

(iii) *The third relates to compulsory licensing*. The proposed amendment provides no scope for compulsory licensing in cases where, notwithstanding the offer of reasonable commercial terms and conditions to the patent holder by an enterprise, the patentee does not respond within a stipulated period of time. In all such cases compulsory licensing is permitted even within the framework of TRIPS Article 31 (a) and (b), and countries like Brazil and China have passed legislation allowing compulsory licensing in such

circumstances. *This omission from the proposed amendment must be remedied forthwith.*

(iv) *Fourthly*, in all cases where compulsory licenses are granted, even though the production is supposed to be "predominantly" for supply in the domestic market of the country in question, *exporting should also be explicitly allowed.* This is particularly important in the case of pharmaceuticals where Indian licensees can export drugs to the African market at low prices, to the mutual benefit of both.

(v) *The fifth relates to "Mail Box" cases*, i.e. where applications have been received during the transitional period 1.1.1995 to 31.12.2004, and patents, if granted, would be effective from the latter date for a period of twenty years from the date of application. In all such cases if any production activity has been started by any enterprise during the transition period, then that enterprise should be allowed to continue production on payment of a nominal royalty to the patent-holder, after the patent has been granted, instead being accused of violating the patent.

(vi) *Sixthly,* the magnitude of royalty payment should be explicitly stipulated within a range, say 4-5 percent, of the sales turnover at ex-factory price.

(vii) *Seventhly,* the existing provision regarding pre-grant opposition to the grant of a patent will be even more relevant in the future with the expanded scope of the Patents Act. The TRIPS Agreement does not preclude the possibility of pre-grant opposition. Some other countries have provided for it. There is no justification for the removal of the existing provision from the Patents Act, as is being proposed in the amendment. Several other changes in the proposed amendments are detailed below, but the main issues are as above.

8. The May elections in the country have brought into office a new government which is committed to providing a "human face" to our integration with the global economy. A Common Minimum Programme embodying greater commitment to the provision of education and health facilities to the people has been drawn up as a charter of governance. To honour that commitment it is essential that the government should confront the attempt of MNCs to buttress their monopoly position at the cost of the people of the country, through the imposition of a particularly coercive version of a TRIPS-compatible patent regime. The purpose of our report, like that of the reports of the previous Commissions, is to make some suggestions on how it should go about doing so.

9. **We have suggested minimal necessary changes in the Patents Amendment Bill 2003 so that while the proposed legislation still remains largely within the**

parameters of the TRIPS Agreement, it does not simply become an instrument to promote the monopoly interests of the MNCs. .The need for a thoroughgoing review of TRIPS, however, can not be overemphasized. The struggle against the unequal treaty of TRIPS needs to be carried forward at the national as well as the multilateral level. To this end, a full -scale national debate is called for. We urge the Government to lead the process by setting up a National Commission on the subject of Intellectual Property Protection, Technological Self -Reliance and People's Welfare. At the multilateral level, we urge the government to reinforce the process of review of the TRIPS Agreement in co-ordination with other developing countries.

Chapter I :

Approach

" My idea of a better ordered world is one in which medical discoveries would be free of patent and there will would be no profiteering from life or death."

Indira Gandhi

[From her address to the World Health Assembly in Geneva

May 6, 1981]

The multilateral trading system embodied in GATT underwent a paradigm shift with the coming into being of WTO. No other element of the new system demonstrates that shift as dramatically as the Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS) That agreement lays down a whole set of international norms, standards and procedures in regard to substantive matters relating to intellectual property rights. The move to bring these issues squarely within the trading system and its enforcement mechanism was patently in favour of the Multinational Corporations (MNCs) and intended to severely restrict the autonomous space available to developing countries for establishing appropriate national regimes to achieve technological development and self- reliance. Even so, the new international regime was sought to be rationalized in the name of providing adequate incentives to expensive R&D, and encouraging flows of investment. It was argued that allowing a few years' period of transition for implementation and some technical assistance would take care of the structural impediments of developing countries. The experience of the last decade has proved the hollowness of these claims. Consequently, developing countries have been emphasizing the need for a review of the TRIPS agreement as part of the implementation issues under negotiations in the Doha Round.

2. It is pertinent to note that economists of repute who otherwise are fully supportive of the free trade theory and the WTO (Jagdish Bhagwati, Dani Rodrik, Michael Finger) have, of late, recognized the inequity of the TRIPS agreement from the point of view of developing countries and some have even questioned the logic of incorporating TRIPS into the WTO system in the first place. Similarly, in its report of September 2002,the Commission on Intellectual Property established by the Government of U.K has made a pointed reference to the likely adverse impact of the global enforcement of the new intellectual property regime on the cost and availability of medicines to developing countries and the need to use the mechanism of "compulsory licensing" to mitigate such impact. In the same vein, The U.K. Royal Society Working Group on Intellectual Property, in their report of April 2003, have drawn attention to (a) the possible "tension between private profit and public good"

caused by monopolies created by IPRs; (b) the "climate of secrecy" encouraged by patents, "which limits the free flows of ideas and information that are vital for successful science"; and (c) the clear possibility that the " benefits that (the TRIPS Agreement) brings to many developing countries may be outweighed by the disadvantages ." It goes further and states categorically: "This restriction of the commons in the main IP areas of patents, copyright and databases rights has changed the balance of rights and hampers scientific endeavour. In the interest of society, the balance must be rectified."

3. The epidemic-like incidence of HIV-AIDS in African countries and theWestern MNC's insensitive response in refusing to make available at affordable prices the drugs necessary for the treatment led, on the one hand, to corrective legislative and administrative action on the part of some governments in Africa to reduce the adverse effects of the new IPR regime, and on the other, to an upsurge of public opinion the world over, including USA and EU, questioning its rationale, particularly in the area of public health. The movement "Doctors without Frontiers"(MSF) provided a powerful voice to this upsurge and soon became a global force contending the rationale of the new IPR regime. The validity of the philosophy underlying our Patents Act of 1970 was also demonstrated when our pharmaceutical companies not constrained by the restrictive product patent regime offered extremely inexpensive alternatives to the African countries. All these developments ultimately resulted in the Doha Declaration on TRIPS Agreement and Public Health (November 1999) seeking to limit, to some extent, the damage done by the TRIPS agreement and its underlying philosophy.

4. In sharp contrast to this changing global perception, we find that as the deadlines envisaged by the TRIPS agreement approach, the process of "aligning" our Patent Law to the norms set out in the TRIPS agreement is being expedited at the national level. We have witnessed two amendment acts (1999 and 2002) and the third one (the Bill of 2003) is already under consideration. While the first two amendments were being processed, the erstwhile People's Commission Reports raised a number of basic issues for consideration of the government. However, the response of the government was that a comprehensive third amendment would soon come up for consideration and that would be the occasion for such consideration. Following that line of reasoning , this is virtually the last window of opportunity for effecting appropriate changes in the proposed legislation.

5. We fully endorse the need for a through-going review of the TRIPS at the multilateral level and would urge the government to reinforce the initiative of developing countries to that end in the WTO. However, placed as the government is in the context of the so-called dead –lines, we consider it equally important to

carefully look for the niches available in the TRIPS agreement as well as the leeway provided by later developments such as the Doha Declaration on TRIPS Agreement and Public Health (November 1999), closely examine their potential and exploit the same in full measure, to mitigate, if not eliminate, some of the severe restrictions and distortions entailed by a simplistic conformist approach towards "aligning" our Patent Act to the TRIPS agreement. **In our view, a more creative and independent approach is called for.**

6. Equally, we must make this exercise consistent with and conducive to the goals of the wider national policies such as the National Health Policy (2002) and the National Pharmaceutical policy (2002). **Above all, we must ensure that the exercise of making our Patent Act "WTO – compliant" does not end up contravening or jeopardizing the fundamental rights that the Constitution guarantees to our people.** As the third People's Commission on Patent Laws pointed out in their report of 2003, the proposed amendments must fully respect the spirit of and conform to the provisions of Articles 13, 14, and 21 of the Constitution. Article 13 enjoins that " the State shall not make any law which takes away or abridges the (fundamental) rights... and any law made in contravention of this clause shall to the extent of the contravention, be void." Article 14 guarantees equality before law: It follows that any law that treats the unequal equally will fall foul of this requirement. Article 21 guarantees protection of life and personal liberty: "No person shall be deprived of his life or personal liberty except according procedure established by law." The Supreme Court has clarified that right to life includes right to health.

7. It will be useful in this background to look at **Articles 7, 8 and 31 of TRIPS agreement** and examine what flexibilities they have.

8. **Article 7** states the "**Objectives"** thus: "The protection and enforcement of intellectual property rights should contribute to promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations. "
It is obvious that the qualifying phrases "to the mutual advantage" and "the balance of rights and obligations" do circumscribe the manner in which the objectives would be realized. Nevertheless, the substantive goals of promoting innovation; transfer and dissemination of technology; and furthering social and economic welfare have been explicitly recognized. And this formulation needs to be interpreted liberally so as to justify the amendments suggested in this report.

9. **Article 8** is titled **"Principles**": " Members may in formulating or amending their national laws and regulations ,adopt measures necessary to protect public health and

nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual rights by right holders or resort to practices which unreasonably restrain or adversely affect the international transfer of technology."

Here too, the qualifying proviso that "measures are consistent with the provisions of the Agreement" does hedge in the scope of measures significantly. The wording is "provided that they are consistent with the provisions of the Agreement" and not: "Notwithstanding the provisions of this Agreement", which makes all the difference and makes it highly restrictive. However, it must be emphasized that the language used to define the purpose for which the measures are to be taken is wide in scope and goes far beyond the concepts of public health and nutrition, and embraces the concept of "public interest" and "socio-economic development" and also visualizes the need for preventing abuse of rights by right holders. The amending legislation must not lose sight of the wide scope of the substantive language defining the purpose of the measures.

10. **Article 31**: **" Other Use Without Authorisation of the Right Holder**". This article does provide a possibility of reducing somewhat the rigour of high protection provided by the TRIPS agreement to the patent holders under well-defined circumstances. At the same time, it lays down conditionalities and norms that must be observed by the law permitting such use. All in all, "the use without authorisation by the right holder"visualized in this Article is a weak proxy for the Compulsory License (not to mention the Licenses of Right) provided for in the Indian Patents Act, 1970. To start with, under the Article, the authorisation of such use is to be considered on a case by case basis: and not in terms of a general and broadly formulated functional criteria as in our Patents Act, to wit, "reasonable requirements of public with respect to the patented invention have not been satisfied or the patented invention is not available to the public at a reasonable price". While our Patents Act simply prescribes expiry of a three year period from the date of the sealing of a patent before the request for a compulsory license is entertained by the authority, the Article enjoins that a request for such use can be entertained only if efforts to obtain authorisation from the right holder on reasonable commercial terms have not been successful within a reasonable period of time. This requirement may be waived only in cases of national emergency /other circumstances of extreme urgency/in cases of public non-commercial use. The Article further stipulates that such use will be predominantly for the supply to domestic market; and that adequate remuneration shall be paid to the right holder. Furthermore, the legal validity of the decisions relating to authorisation

of such use and adequate remuneration shall be subject to judicial review. Only strong exception provided is in the context of the need to correct anti-competitive practices The *raison de etre* of the Trips agreement is to strengthen the patent monopoly. In the circumstances, the direct and effective remedy against anti-competitive practices embedded in the strengthened patent monopoly would lie in providing a liberal regime for use without authorisation of the right holder. Instead of this, the Article follows the convoluted route of first narrowing down and hedging in the exception which makes such use possible and then seeking to provide a limited exception to that exception.

11. In this background, our approach in this respect is guided, by the imperative need to preserve, to the largest extent possible, the crucial provisions of the Patents Act 1970 in the shape of Compulsory Licenses and Licenses of Right, rather than by the simplistic stance of substitution of the extant provisions by the language of the Article or even worse, as appears to be the case in the proposed legislation.

12. **The Doha Declaration of November 2001** avers that "The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose..... These flexibilities include: .... Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted..."

13. The Declaration is admittedly in the context of the Public Health and, therefore, the specific flexibilities that it refers to and the use thereof that it speaks of have limited applicability. Moreover, it avers the general "commitment to the TRIPS Agreement" and also explicitly reaffirms the resolve to "maintain commitments in the TRIPS Agreement". The so-called solution to the problems of countries with insufficient or no manufacturing capacities in the pharmaceutical sector that the Declaration has finally led to is of little practical significance as that solution is riddled with prior conditionalities and demanding procedural requirements. These constitute the obvious shortcomings and limitations of the Doha Declaration. Nevertheless, the very fact that in the critical pharmaceutical sector, it recognizes the primacy of public health concerns over the concerns of IPRs and goes to the extent of specifically recognizing the modality of compulsory licensing, which was always an anathema to the protagonists of strong IPRs (such as the coalition of the pharmaceutical industries in USA, EU and Japan) is indicative of the changing times

and the possibility, however small, of reducing the inherent inequity of the TRIPS agreement. And we believe that we must seize that opening and explore the farthest limits of introducing similar changes in the proposed legislation.

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Chapter 2

Major Issues and Recommendations.

The Patents Act 1970 was enacted on the basis of a comprehensive Report of 1959 by Justice N.Rajagopala Ayyangar on the "Revision of the Patent Laws" and in depth deliberations during the 1960s in the Joint Parliamentary Committee set up on this subject. There was also an extensive debate in both the Houses of Parliament before the adoption of the 1970 Act. The 1970 legislation was aimed at attaining the following important objectives:

(i) Raising the technological level of the Indian economy by facilitating indigenous development, adaptation and transfer of technology;

(ii) Ensuring that the fruits of technological innovations become available to all the sections in society; serving other public purposes, particularly public health;

(iii) Ensuring a competitive environment in the industrial sector;

(iv) Protecting the domestic enterprises from the adverse effects of monopoly in knowledge and technology;

(v) Contributing to meeting the Constitutional obligations of the State under the Fundamental Rights, particularly the 'right to life', guaranteed to the citizens of the country.

2. These objectives were sought to be realized by the following important provisions in the Act:

(a) Exclusion of certain products and processes from the ambit of patenting;

(b) Not providing product patent in the food, medicine, drugs, pharmaceutical and chemical-based products;

(c) The provision for the grant of only process patent in these sectors and that too for a short term of 5/7 years;

(d) Making provision for compulsory licences and providing for 'licences of right';

(e) Insistence on working of patents in the country and revocation for non-working;

(f) Putting a ceiling on royalty payment.

3. During over 3 decades of the application of the patent system envisaged in the 1970 Act, the pharmaceutical industry in India registered a spectacular growth and it became possible to make medicines available to the people at prices lowest in the world. A comparative statement showing the prices of medicines in India and those prevailing in other countries is given at Annexure-2.

4. The Indian pharmaceutical industry is not only meeting the demands in the country but is also producing in sufficient quantity and range to be able to export a part of its production to both developed and developing countries. About half a dozen Indian companies have now become major players in the international markets. Latest data, including comparison with past growth in production and exports of pharmaceutical products by the pharmaceutical industry in India, are given in Annexure-3.

5. As a member of the WTO, India is committed to amend the Patents Act of 1970 in order to bring it in conformity with the provisions of the TRIPS Agreement. But in doing so the above-mentioned broader objectives underlying the 1970 Act, must not be compromised. Unfortunately, in the two amendments to the 1970 Act carried out in 1999 and 2002 and in the draft Bill of December 2003 at present under the consideration of the Government, several of these objectives have been diluted or lost sight of. Moreover, drafting the Bill, the Government has not been able fully to make a creative use of the flexibility provided in Articles 7 & 8 of the TRIPS Agreement and in the Doha Declaration on TRIPS Agreement and Public Health. The amending Bill also does not take into account the legitimate demands of the developing countries, in the formulation and articulation of which India has played a leading role, for the revision of the TRIPS Agreement in order to bring it in conformity with the Convention on Bio-Diversity and to remove some of the inherent inequities and imbalances in the TRIPS Agreement..

6. A sound and balanced national patent system is of crucial importance for the autonomous development of any economy and for meeting public demand for drugs, pharmaceuticals and other essential commodities. It is, therefore, extremely important that every provision of the amending Bill should be formulated with utmost care and attention and with clarity and precision. The important components of the Patent system are as follows:-

(a) Scope and Patentability;

(b) Compulsory licensing, in order to enable the domestic enterprises to ensure abundant availability at competitive prices, of pharmaceuticals and other products covered by the patent regime;

(c) The terms of patent i.e. period of patent and licenses;

(d) Royalty parameters;

(e) Export of patented products; and

(f) Pre-grant opposition to patent claims.

7. We have examined the provisions of the proposed legislation under the headings of the above components and in the paragraphs that follow, we have tried to bring out the deficiencies in the amending Bill and advanced specific suggestions for removing them.

A. Scope of Patentability:

Definition:

8. There is a large number of terminologies used in any patent legislation. The definition of such terminologies has an important bearing on the scope of the patent legislation and on patentability. Some of the key terminologies need to be defined carefully to limit the scope of patentability, to leave sufficient space for sovereign policy making and to prevent filing of frivolous applications for seeking patent rights. Proper definition also helps in assessing the validity of claiming exclusivity and provides maximum flexibility in compulsory licensing. The nomenclatures which need to be defined carefully are "Invention", "Novel Invention" and "pharmaceutical substances". We make the following recommendations with regard to the definition of these terminologies:

(a) "Invention" should be defined as "a basic novel product or process involving inventive step and capable of industrial application."

(b) "New or novel inventions" should mean "any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of the filing of the patent application with complete specification i.e. a subject matter that has not fallen in public domain or formed part of the state of the art."

(c) **"Pharmaceutical substances" should be defined as "new chemical entity or new medical entity involving inventive steps."**

On definitions and patentable subject matter many other countries has taken special care for making suitable provision. Extracts from patent laws of other countries are reproduced in Appendix III-Part A

B. Patentability:

9. The draft Bill suggests the deletion of section 5 of the 1970 Act on Patentable subject matter. We feel that this is a basic component of a patent system and must be provided in the legislation. We, therefore, suggest that the Bill should provide that:

"Patent should be available for basic novel inventions including pharmaceutical substances whether products or processes, in all fields of technologies but excluding inventions not patentable, provided that they are new, involve an inventive step and are capable of industrial application".

10. A creative interpretation of the relevant Articles of the TRIPS Agreement and of the Doha Declaration on the TRIPS Agreement and Public Health would warrant that in defining patentability, our legislation should not strictly follow the provisions of Article 27(3)(b) of the TRIPS Agreement. In the review of the TRIPS Agreement, the developing countries have asked for the exclusion of certain products and processes covered under Article 27(3)(b) . There is no reason for our proposed legislation to include these items until the review is completed. The exclusion clause(j) should, therefore, be formulated along the following lines:

(j) Plants, animals and micro-organisms in whole or in part or constituent thereof including seeds and their varieties and species, and any process including all biological, non-biological and micro-biological processes for production or propagation of plants, animals and micro-organisms.

11. We also propose that the legislation "should not include inventions which do not strictly meet the criteria of Industrial application e.g. onco mouse; stem cell, partial gene fragments; research tools, PCR techniques, machine-based embedded bio-informatics software, genomic information and data base. In addition to these all or parts of naturally living beings, including micro-organisms in any form and biological materials found in nature or isolated there from including germ plasm or

any living being and any biological processes, single nucleotide polymorphisms, naturally occurring macromolecules such as DNA, proteins or modified proteins.

C. Compulsory Licensing:

12. Compulsory licensing is the core aspect of a patent system. It helps ensure the crucial role of the domestic enterprises in meeting the ever increasing demands of patented products, particularly pharmaceuticals, at competitive prices. Developing countries, particularly those which have a strong pharmaceutical and other industries whose products are subject to product patent, cannot afford to depend for the availability of these products on monopolistic foreign sources at monopolistic prices. Countries like India, China, Brazil, Argentia and Egypt have strong pharmaceutical and other industries which cannot be prevented from playing a major role in ensuring the availability of the patented products at competitive prices. With the demand growing quite fast, the role of the domestic industry has also to grow. The Indian pharmaceutical industry, in particular, has been providing medicines at prices lowest in the world. Their role has to be strengthened in the product patent regime.

13. As already explained in Chapter I, the Doha Declaration on the TRIPS Agreement and Public Health has given adequate freedom and flexibility to member countries to grant compulsory licences in the pharmaceutical sector, and to determine the grounds on which and the circumstances in which such licenses could be granted.

14. Articles 7 & 8 of the TRIPS Agreement also provide enough flexibility for granting compulsory licences for the promotion of technological innovation and for the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and also to protect public health and nutrition and to promote other public interests in sectors of vital importance for socio-economic and technological development. Article 31 of the TRIPS Agreement stipulates many possibilities for grant of compulsory licences. Even Article 5 of the Paris Convention envisages the possibility for the grant of compulsory licences.

15. The following are some of the purposes and circumstances justifying the grant of compulsory licences:-

(a) For Government use by government enterprises or third parties authorised by the government (Article 31 of the TRIPS Agreement);

(b) Preventing abuse of patent rights in the form of charging higher prices and letting demand remain unsatisfied (Article 5 of the Paris Convention and Articles 7 & 8 of the TRIPS Agreement);

(c) Giving licenses for commercial activity in a situation where in spite of offering to the patent holder, commercial terms and conditions, the offer of the domestic enterprise remains unsuccessful for a reasonable period (Article 31.b of the TRIPS Agreement);

(d) Remedying anti-competitive practices (Article 31.k);

(e) Grant of second patent due to a significant improvement over the first patent (Article 31.f of the TRIPS Agreement);

(f) Authorising licences in situations of national emergency, circumstances of extreme emergency or public non-commercial use (Article 31.b of the TRIPS Agreement).

16. To cover the points (c) mentioned above, we recommend that the formulation on compulsory licensing in the new legislation should be couched in as flexible a language as possible, somewhat along the following lines:

> **Where the proposed user has made efforts to obtain authorisation from the patentee to use the Patent on reasonable commercial terms and conditions and where such efforts have not been successful within a reasonable period of time, the Controller shall at any time after the expiration of three years from the grant of the patent, grant compulsory licence to the applicant on such terms and conditions as he may deem fit.**

Examples of many other countries making provision for compulsory licence for such a contingency are given in Appendix III Part B

17. In addition there should be a clause on "licence of right" also. Article 7 of the TRIPS Agreement mentions the transfer and dissemination of technology as one of the objectives of the Agreement. Keeping this in view, **'it will be important to retain the freedom to issue licence of right' at least for process patent. The wording could be on similar lines as in sections 86-88 of the 1970 Act.** Such a provision, among others, will help in promoting new patented technologies by involving several other enterprises in exploiting the product in various regions of the country. As regards the extension of this right to product patent, the issue should be taken up in the process of the review of the TRIPS Agreement in WTO.

D. Term of Patent:

18. According to Article 33 of the TRIPS Agreement, the term of patent protection stipulated is for a period of 20 years counted from the filing date. However, as regards the term of patent for applications received during the transitional period of 10 years i.e. from 1-1-1995 to 31-12-2004, for pharmaceutical

and agricultural chemical products, the provisions in Article 70.8 (c) of the TRIPS Agreement should be kept in view. This Article provides that Patent protection on transitional period applications has to be provided from the date of the grant of the patent and for the remainder of the patent term counted from the filing date in accordance with Article 33 of the TRIPS Agreement for those of the applications that meet the criteria for protection.

Since the patent rights would be available from the date the patent rights are actually granted, any production activity of the concerned product started by any other enterprise during the transitional period and prior to the grant of patent rights, should not be treated as infringement of patent rights. The concerned enterprise should be allowed to continue production on payment of royalty to the patent holder. If enterprises are asked to stop production, there may be shortage of supply and the products may not be available at affordable prices. There are already examples of grant of exclusive marketing rights to multinational companies leading to the stoppage of production and marketing of these drugs by Indian companies in spite of the fact that they had been selling their products for quite some time and at prices almost one-tenth or one fifteenth of the prices of the EMR holders. It will, therefore, be necessary to make a provision in the amending legislation to take this particular interest into account keeping in view in particular the provisions of Article 70.8 (c) of the TRIPS Agreement.

19. Under Article 70.8(b) of the TRIPS Agreement, all applications received during the transitional period 1-1-1995 to 31-12-2004 are to be examined for their eligibility for the grant of product patent w.e.f. 1-1-2005. Moreover, according to Article 70.3 of the TRIPS Agreement, subject matters which have fallen in the public domain as on 1-1-2005, shall not be eligible for Patent protection. It is necessary to make suitable provisions in the new legislation covering all these points. We suggest the following formulation:

(a) All products patent applications received during 1-1-1995 to 31-12-2004 shall be examined with regard to their eligibility for the grant of patent;

(b) There shall be no obligation to restore protection to a subject matter which on 1-1-2005 has fallen in the public domain;

(c) In regard to applications received during the transitional period for product patents for pharmaceuticals and agricultural chemicals, protection would be provided as from the date of the grant of the patent and for the remainder of the patent term counted from the filing date, for those applicants which meet the criteria for protection;

(d) **The Patent protection on such applications shall be provided as from the date on which the determination to this effect is made and as such no infringement proceedings shall be instituted against any enterprise which made significant investment and is producing and marketing the concerned product prior to the grant of patent on such applications. The Patent right holder will, however, be entitled to receive royalty from such enterprises on and after the grant of Patent.**

20. It is necessary to specify the term 'reasonable period' in the legislation so as to avoid unnecessary litigations and arbitrary judicial verdicts. The proposed Bill should, therefore, provide as follows:

The reasonable period after which the applicant may approach the Controller would not be less than 150 days from the date he had approached the patentee.

E. Royalty Parameters:

21. Article 31(h) of the TRIPS Agreement provides that the right holder 'should be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation'. There is a need to stipulate parameters which should determine the appropriate amount of royalty. These could include the utility and scope of the product for the country and sale turnover at ex-factory sale price. It may also be prudent to suggest a ceiling on royalty payment in terms of a percentage of the annual sales turnover. The practice followed by some of the countries in this regard is Canada (4 percent), US (5 percent), Japan (2 to 4 percent), Germany (2 to 10 percent. **In our legislation we could provide not exceeding 5 percent of sales turnover for royalty payment.**

F. Export of Patented Product:

22. Article 31(f) of the TRIPS Agreement provides that compulsory licenses would be authorised predominantly for the supply to the domestic market of the country concerned. The use of the word 'predominantly' provides an avenue for exports to other countries. **National legislation should, therefore, provide that the compulsory license holder will have the right to produce some quantity of the patented product for exports also.**

23. As regards pharmaceutical products in particular, paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health stipulated a expeditious solution to the problem of those countries which are having insufficient or no manufacturing capacity in the pharmaceutical sector for making use of the flexibility provided in the Declaration. The General Council of the WTO later took a decision on the procedure to be followed for meeting the needs of such countries. The procedure was proposed by USA and agreed upon by other countries, including India. It is quite cumbersome and even unworkable. The smaller countries having only insufficient or no manufacturing capacity, would have small requirements of their patented pharmaceutical products. No enterprise in other developing countries would seek compulsory license only to produce small quantities for these countries, as it would not be economically viable.

24. Moreover, in order to produce a new drug some research effort is also involved which may require a period of at least 2 to 3 years to bear fruit. Therefore, the stipulation in the procedure for producing exclusively for the supply of the product to these small countries does not seem to be practicable. The demand of countries in this category can be met only by those compulsory licence holders who are already producing for domestic markets and have surplus capacity to meet export demands. Therefore, the provision on the grant of compulsory licence for the specific purpose of supply to smaller countries has to be flexible and simple. The procedure as recommended by the General Council of WTO needs to be reviewed from practical difficulties point of view.

25. Taking the above factors into account, the proposed legislation should be re-written stipulating export provision in an unambiguous manner, along the following lines:

(a) The license is granted mainly for the purpose of supply in the Indian market but also for the export of the patented products to other markets, if need be;

(b) In case where license is granted to remedy any practice which is determined through judicial or administrative process to be anti-competitive, the licensee should be permitted to export the patented product.

G. Pre-grant Opposition to Patent Claims:

26. In a country which is changing its patent laws in order to extend product patent provision to all industrial sectors, including the pharmaceutical sector, the continuation of the provision in the 1970 Act, relating to the opposition to the grant of

patents before the patent is actually granted, is absolutely necessary. The TRIPS Agreement is silent on this point. There are examples of such provisions in the patent laws of a number of countries. There is, therefore, no reason why we should change our existing provision, particularly when there has been no complaint about it during the period of the three decades that the 1970 Act has been in operation. This is particularly so when the provision allowing opportunity for pre-grant opposition, makes for transparency and is, therefore, in democratic spirit. We, therefore, propose that the democratic provision for pre-grant opposition in the 1970 Patent Act should be retained without any modification. The examples of other countries having provision for pre-grant opposition are given in Appendix III Part C.

H. Transfer of Technology

27. Articles 7 and 8 unambiguously provide for transfer and dissemination of technology as an objective and principle of TRIPS Agreement. This stipulation is extremely important for implementation of compulsory licence. In the amending process however, this provision has been ignored. A specific provision has been suggested in a new Section 95.

28. Specific amendments to the text of the proposed Bill are given in Appendix-I to this Chapter which also includes, for convenience of comparison, the relevant text in the proposed Bill. The examples of other countries, specifically on the scope of patentability, is given in Appendix-III, Part-A, to this Chapter.

29. In addition, we have suggested a series of amendments for imparting greater precision, clarity and logic to the provisions in the proposed Bill, for removing inconsistency and equivocation in its formulations, for ensuring that there are no unwarranted omissions and deletions, and for otherwise refining some of these provisions. These are contained in Appendix-II to this Chapter.

Important provisions of Amended Patents Act 1970 (After 1999 and 2002 amendments and provision in draft Patents Amendment Bill 2003) and amendments suggested

I. Section 2: Definitions and interpretation

Sub-section 1

(i) Clause (j) :

(j) "invention" means a new product or process involving an inventive step and capable of industrial application

Section 2 : Definitions and interpretation

Sub-section 1
Clause (j) :

(j) "invention" means a 'basic novel product or process involving inventive step and capable of industrial application ;

(Remark : patentable invention should be basic novel product or process. This will help in regulating volume of application to a manageable level)

(ii) New clause (la) :

"New or novel invention"

A new clause (la) may be incorporated as follows :

(la) "new or novel invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.

(Remark : It is important to provide the definition of 'New or novel' invention which is an important criteria for admitting claims many countries even define prior art also)

(iii) New clause (ta) :

"Pharmaceutical substances"

A new clause (ta) may be incorporated as follows :

(ta) "pharmaceutical substance" includes, new chemical entity or new medical entity involving inventive steps".

(Remark : Proposed definition is based upon the recommendations of the Pharmaceutical Research and Development Committee headed by Dr. R.A. Mashelkar)

II. Section 3 : What are not inventions

Clause (j) :

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals ;

Clause (j) : may be incorporated as follows :

(j) plants, animals and microorganisms in whole or in part or constituent thereof including seeds, varieties and species and any process, including essentially biological, non-biological and micro-biological processes for production or propagation of plants, animals and microorganisms (the term microorganism here would include viruses) ;

(Remark : Review process of Article 27(3)(b) of TRIPS Agreement for patenting of "micro-organisms and non-biological and microbiological processes" by the WTO is still not complete and as such provision thereof should be excluded. Alternatively their patenting should be given effect to only after the review by the WTO has been completed)

III. Section – 5*

(1) In the case of inventions –

(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or

(b) relating to substances prepared or produced by chemical process (including alloys, optical glass, semi- conductors and inter-metallic compounds) no patent shall be granted in respect of claim for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

(2) Notwithstanding anything contained in sub-clause (1), a claim for patent of an invention for a substance itself intended for use or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA "Explanation – For the purposes of this section "chemical process" includes biochemical, biotechnological and microbiological process.

Section 5

Sub-clause (2) was introduced through the Patents (Amendment) Act, 1999 and the explanation was incorporated through Patents (Second Amendment) Act 2002. Instead of omitting this section as suggested in the draft Bill 2003, the following should be substitutive :

5(1) Patents shall be available for basic novel inventions including pharmaceutical substances as defined in section 2 whether products or processes in all fields of technologies excluding inventions stipulated under Section – 3 provided that they are new, involve an inventive step and are capable of industrial application

(2) All product patent applications received during 1.1.1995 to 31.12.2004 shall be examined as provided in sub-clause (1) of this section.

(3) There shall be no obligation to restore protection to a subject matter which on 1.1.2005 has fallen in the public domain.

Explanation – For the purpose of this section, the term "inventive step" and "capable of industrial application" may be deemed to be synonymous with the term "non-obvious and "useful" respectively.

(Remark : All applications received during the transitional period 1.1.1995 – 31.12.2004 according to Article 70.8(b) of TRIPS Agreement are to be examined as provided for product patent regime from 1.1.2005. Further according to Article 70.3 of TRIPS Agreement any subject matter which had
fallen in public domain as on 1.1.2005 i.e. the date of application of TRIPS provision on product patents for applications received during 1.1.1995 – 31.12.2004 shall not be eligible for patent protection).

*The **above Section (5)** has been proposed for deletion in the Draft Patents (Amendment) Bill 2003. Alternative provision on this important aspect of the patents system should not have been ignored.

IV Section 11 (A)

New sub-section (7A)

Transitional Arrangement applications.

Section 11 (A)

New sub-section (7A)

7(A) However the provisions of sub-section (7) shall not apply to applications filed during the period 1.1.1995 – 31.12.2004. The patents protection on such applications shall be provided as from the grant of the patents and as such no infringement proceeding shall be instituted against any enterprise which made significant investment and is producing and marketing the concerned product prior to grant of patent on such applications.. The patent right holder will however be entitled to receive nominal royalty from such enterprises on and after the grant of patent

(Remarks: The provision is based upon Article 70.8 (c) of TRIPS Agreement)

V. Sections 25 – 28 Pre-grant Opposition

The proposal to amend Chapter V (Sections 25 – 28) is not based upon any requirement of the TRIPS Agreement. This chapter provides for democratic provision for pre-grant opposition of patent and as such should be retained without any modification.

VI. Section 53 : Term of patent :

New sub-section (2) :

New sub-section (2) may be incorporated as follows :

2. In regard to applications received during the period 1.1.1995 to 31.12.2004 for product patents for pharmaceuticals and agricultural chemical, protection would be provided as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with sub-section (1) of this section for those of the applications that meet the criteria for protection referred to in Section 5 of this Act.

(Remark : sub-section (2) is based upon Article 70(8)(c) of TRIPS Agreement).

Sub-sections (2), (3) and (4) of this section shall be renumbered as (3), (4) and (5)

VII. New section 84 (B) :

section 84 (B)

A new Section 84 (B) may be incorporated as follows :

(1) Where the proposed user has made efforts to obtain authorization from the patentee to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time, the Controller shall at any time after the expiration of three years from the date of grant of patent, grant compulsory licence to the applicant on such terms and conditions as he may deem fit ;

(2) The reasonable period after which the applicant may approach the Controller would not be less than 150 days from the date he had approached the patentee. The commercial terms and conditions offered by the applicant shall be considered reasonable by the Controller if royalty and other remunerations offered by him are within five percent of the annual sales turnover of net ex-factory sale price.

(Remark : The suggested provision is extremely important and is within the framework of TRIPS Article 31 (a) and (b).Many other countries have also provided such a provision in their patent laws. Other countries like China, Brazil etc. have made similar provision in their patent laws)

VIII. Section 90 clause VII

(vii) that the licence is granted with a predominant purpose of supplying in Indian market and in the case of semi- conductor technology, the licence granted is to work the invention for public non-commercial use and in the case, the licence granted to remedy a practice determined after judicial or administrative process to be anti-competitive, licensee shall be permitted to export the patented product ;

clause (vii) needs to be re-written stipulating export provision in an unambiguous manner as follows :

(vii) (a) that the licence is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be ;

(vii) (b) that in the case of semi-conductor technology the licence granted is to work the invention for public non-commercial use ;

(vii) (c) that in case, the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product if need be.

(Remark : Clause (vii) as provided need to be stipulated separating for each contingency)

Other amendments/substitution suggested to the Amended Patents Act 1970 and provisions proposed in draft Patents (Amendment) Bill 2003

CHAPTER I : PRELIMINARY

Section 2 : Definitions and interpretation

Sub-section 1

1. **Clause (ac)**

(ac) "capable of industrial application", in relation to an invention means that the invention is capable of being made or used in an industry ;

The words 'an industry' may be substituted by the words 'any industry'.

(Remark : use of word 'any' will have a broader application)

2. **Clause (f) :**

(f) "exclusive licence" means a licence from a patentee which confers on the licensee, or on the licensee and persons authorised by him, to the exclusion of all other persons (including the patentee), any right in respect of the patented invention, and exclusive licensee shall be construed accordingly ;

After the words 'from a patentee' the words 'or the Controller' may be added.

(Remark : Excepting the voluntary licence all other licences are to be granted by the Controller, the suggested amendment is made accordingly)

3. **Clause (ja) :**

(ja) "inventive step" means a feature that makes the invention not obvious to a person skilled in the art ;

Clause (ja) may be substituted as follows :

(ja) "inventive step" means a feature of an invention that involves important technical advance as compared to the existing knowledge and or having considerable economic significance and that makes the invention not obvious to a person skilled in the art ;

(Remark : there is a need to provide expanded version as proposed)

4. **Clause (l) proposed in Draft Patents (Amendment) Bill 2003**

(l) Opposition Board "means an Opposition Board constituted under sub-section (4) of Section 25.

This clause may be deleted as the amendment proposed under Section 25 (4) should not be carriedout. Section 25 should be retained as amended under Patents (Second Amendment) Act 2002.

5. **Clause (o)**

"patented article" and "patented process" means respectively an article or process in respect of which a patent is in force.

Clause (o) may be substituted as follows :

"patented article" and "patented process" mean patented article or article produced by the patented process and patented process in respect of which patents are in force.

(Remark : clause (a) of Section 82 may be deleted as the definition therein has now been proposed to be covered by clause (o) above).

6. **Clause (p)**

"patentee means the person for the time being entered in the register as the grantee or proprietor of the patent.

Clause (p) may be substituted as follows :

"patentee" means the person for the time being entered in the register as grantee or proprietor of the patent. Patentee shall include exclusive licensee.

(Remark : clause (b) of Section 82 may be deleted as the definition therein has been proposed to be covered by clause (p) above)

7. A new clause (xa) may be incorporated as follows :

(xa) 'register of licences' means the register of compulsory licences granted under various sections of Chapter XVI

(Remark : There is a need to have register for licences issued to third parties for use of patents)

CHAPTER II : INVENTIONS NOT PATENTABLE :

Section 3 : What are not inventions

8. **Clause (b) :**

(b) an invention the primary or intended use of commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment ;

Clause (b) may be substituted as follows :

(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human and animal health or plant life or to the environment.

(Remark : Human and animal should only be covered from health angle).

9. **Clause (d) :**

(d) the mere discovery of any new property or mere new use proposed in Draft Patents (Amendment) Bill 2003 for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs atleast one new reactant ;

Clause (d) may be substituted as follows :

(d) the mere discovery of any new property or new use for a known substance or a combination of known drugs or a new formulation of existing drug, or a new variant or polymorph of an existing drug or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs atleast one reactant ;

Explanation : innovative technologies for formulations could be such as 'new drug delivery form' developed on the basis of a novel platform technology and should be covered by process patent.

(Remark :There is a need for excluding frivolous claims as suggested)

10. **Clause (i) :**

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products ;

The words 'or plant' may be inserted after the words 'treatment of animals"

(Remark : inclusion of treatment of 'plants' is also necessary)

11. New clause (ja) may be incorporated as follows :

(ja) inventions which do not strictly meet the criteria of industrial application e.g. onco mouse, stem cell, partial gene fragments, research tools, PCR technique, machine based embedded bio-informatics software, genomic information and data bases ;

12. New clause (jb) may be incorporated as follows :

(jb) all or parts of natural living beings, in any form and biological materials found in nature or isolated therefrom including germ plasm of any living being and any biological process, single nucleotide polymorphisms, naturally occurring macromolecules such as DNA, proteins or modified proteins;

13. New clause (jc) may be incorporated as follows :

(jc) biotechnological inventions needing the use of biological resources ;

14. **Clause (p)**

an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Clause (p) may be substituted as follows :

an invention which, in effect is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, of traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components or compounds.

(Remark : This clause needs to be expanded as suggested)

CHAPTER IV: PUBLICATION AND EXAMINATION OF APPLICATION

15. **Section 11 (A)**

sub-section (5)

"(5) The publication of every application under this section shall include the particulars of the date of application, number of application, name and address of applicant identifying the application and an abstract"

Section 11 (A)

Sub-section (5) :

The words 'of invention disclosed and other information that the Controller in the circumstances deem fit' may be added at the end of the sub-section.

CHAPTER VII : PROVISION FOR SECRECY OF CERTAIN INVENTIONS

16. **Section 39**

Sub-section (2)

(2) The Controller shall expeditiously dispose of every such application within a period not exceeding six weeks :

Provided that if the invention is relevant for defense purpose or atomic energy, the Controller shall not grant the permit without the prior consent of the Central Government.

The words 'or biological materials or traditional knowledge and any other subject matter of strategic importance that may be notified by the government from time to time' may be inserted after the words 'atomic energy'.

CHAPTER VIII : GRANT OF PATENTS AND RIGHTS CONFERRED THEREBY

Section 47 :

17. **Sub-section (3) :***

(3) Any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experimenting or research including the imparting of instructions to pupils; and

Section 47 :

The word "merely" may be deleted.

(Remarks : The word 'merely' has been deleted as the same can be misused).

CHAPTER XII : SURRENDER AND REVOCATION OF PATENTS

18. **Section 66 Revocation of patents in public interest** :

A new sub-section (2) may be incorporated as follows :

"(2) Where import of any patented material/substance is blocked for political or any other reason by the patentee, the central government shall revoke the patent without giving any reason or notice".

CHAPTER XVI : WORKING OF PATENT COMPULSORY LICENCE AND REVOCATION

19. **Section 82 : Definitions** :

82. In this Chapter unless the context otherwise requires, –

(a) "patented articles" includes any article made by a patented process ;

(b) "patentee" includes an exclusive licensee

Section 82 : Definitions :

In this Chapter unless the context otherwise requires -

(a) and (b) May be omitted as the amended definitions has been provided in Section 2.

20. **Section 83**
Sub-section (f)

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title interest on patent from the patentee does not resort to practices whice unreasonably restrain trade or adversely affect the international transfer of technology ; and

Sub-section (f)

The words "and the patentee …….. from the patentee" may be deleted as they are repetition.

Section 84 :

21. **Sub-section (1) (c)**

(c) that the patented invention is not worked in the territory of India

Sub-section (1) (c) may be substituted as follows :

(c) that the patented invention is not worked in different regions in the territory of India.

22. **Sub-section (2)**

Sub-section (2)

'in different regions' may be added after the words "that the patented invention is not worked"

23. **Sub-section (5)**

Where the Controller directs the patentee to grant a licence he may as incidental thereto exercise the powers set out in Section 88.

Sub-section (5)

Since the compulsory licences will be granted by the Controller, the words 'direct the patentee to' should be deleted. The word 'grant' may be changed to 'grants'

24. **sub-section (6) (iv)**

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit :

Provided that the clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public noncommercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

Sub-section (6) (iv) May be deleted.

(Remark: The entire sub-section along with the proviso may be deleted. There is no question of justifying the abuse to the patentee by the applicant. There is no logic in providing this condition. There is also no need of providing the proviso)

Section 85 : Revocation of <u>patents</u> by the Controller for non-working :

25. **Sub-section (1)**

(1) Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements or that the patented invention is not available to the public at a reasonable affordable price.

Section 85 : Revocation of <u>licence</u> by the Controller for non-working.
The word 'patent' in the title may be substituted by the word 'licence'.

Sub-section (1) may be substituted as follows :

(1) Where in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of

two years from the date of the order granting the compulsory licence, apply to the Controller for an order revoking the licence on the ground that the patented invention has not been worked by the licensee in the territory of India.

(Remark : Revoking of the compulsory licence for any reason other than non-working would not be justified. Under other circumstances the justification could be for grant of more compulsory licences to other interested enterprises.)

26. **sub-section 3**

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention has not been satisfied or that patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.

Sub-section (3)

The words "either by the patentee or by the licensees" may be inserted after affordable price.

(Remark : The amendment proposed is based upon Article 5 (3) of Paris Convention.

27. **Section 89**

Clause (a)

(a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;

(a) the word "fullest" may be substituted by the word "maximum"

(Remark : For a large country like India a particular compulsory licence may not be worked to meet the full requirement of the country. The intention should be to work the invention to the maximum extent practicable and for shortfall in availability more compulsory licences could be given).

Section 90

27. Sub-section (1)

clause (ii)

(ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him ;

Clause (ii)

The words 'fullest extent' may be substituted by the words 'maximum extent' possible.

Clause (vi) :

(vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest.

Clause (vi) May be substituted as follows :

(vi) that the licence is for the balance term of the patent.

(Remark :A shorter term cannot be determined and as such it should not be prescribed in the law. Also no one would take licence for a shorter period and invest money and efforts. The spirit of Article 31(g) also does not stipulate 'shorter term'. It only envisages review of stipulated term.).

29. **Sub-section (3)**

(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do, in the public interest, direct the Controller at any time to authorize any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the royalty and other remuneration, if any, payable to the patentee, the quantum of import, the sale price of the imported article and the period of importation), and thereupon the Controller shall give effect to the directions.

Sub-section (3)

The words "the royalty and other remunerations, if any, payable to the patentee" may be deleted.

(Remark : The question of paying any royalty and other remuneration on imported patented product should not arise as imported price would have already included the element of royalty/profit)

30. **Section 95 : Transfer of technology** :

A new Section 95 may be incorporated as follows :

(95) It shall be incumbent upon the patentee to transfer technology to the licensee to manufacture the patented product for which a compulsory licence or authorisation has been granted by the Controller. If the patent holder does not co-operate in the transfer and dissemination of technology the issue of appropriate measures could be considered by the designated authority.

(Remarks: Application of para 5(1) of Doha Declaration on TRIPS and Articles 7 and 8 of TRIPS fully justify transfer and dissemination of technology and taking of measures necessary where the patentees do not co-operate).

CHAPTER XVIII : SUITS CONCERINING INERINGEMENT OF PATENTS

Section 107 A : Certain acts not to be considered as infringement

31. **107 A. For the purposes of this Act,-**

(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or importing of any product ;

(b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as a infringement of patent rights.

107 A. May be substituted as follows :

(a) any act of making, constructing, using, selling or importing a patented invention for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, that regulates the manufacture, construction, use, sale or importing of any product;

(b) importation of a patented product at cheaper prices or to meet the shortages in the country by any person authorised by the Controller from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of the patents rights.

PATENT LAWS OF OTHER COUNTRIES : IMPORTANT COMPONENTS

In order to provide appropriate provision in our finally amended Patents Act 1970 in regard to important patent components relating to : 'scope of patentability', 'compulsory licensing for commercial activity' and 'pre-grant opposition on patent claims', comparative provisions in the patent laws of other countries are reproduced in Appendix III in Parts A,B and C.

PART A – SCOPE OF PATENTABILITY

Relevant extracts from the Patent Laws of Argentina, Australia, Brazil, Canada, China, Chile, France, Indonesia, Israel, Japan, Pakistan, Thailand and United Kingdom reproduced as follows :

I. ARGENTINA :

Scope of Patentability :

The Patents Act of Argentina (1996) provides for patentability as follows :

Article 4. "Inventions relating to products or processes shall be patentable provided that they are new, involve an inventive step and are susceptible of industrial application.

(a) For the purposes of this Law any human creation that permits material or energy to be transformed for exploitation by marr shall be considered an invention.
(b) Any invention that is not included in the state of the art shall likewise be considered novel.
(c) That state of the art shall be understood to be the whole body of technical knowledge that has been made public prior to the filing date of the patent application, or the date of recognized priority if any by oral or written description, by exploitation or by any other means of dissemination or communication of information, either within the country or abroad.
(d) There shall be an inventive step where the creative process or the results thereof cannot readily be deduced by a person of average skill in the technical field concerned.
(e) There shall be industrial applicability where the subject matter of the invention causes as industrial result or product to be obtained, industry being understood as including agriculture, forestry, livestock breeding, fisheries, mining, processing industries in the strict sense and services".

II. AUSTRALIA :

PATENTS ACT 1990 – SECT 18
Patentable inventions

Patentable inventions for the purposes of a standard patent

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:
(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies ; and
(b) when compared with the prior are base as it existed before the priority date of that claim :
(i) is novel ; and
(ii) involves an inventive step ; and
(c) is useful; and
(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Patentable inventions for the purposes of an innovation patent

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim :

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
(b) when compared with the prior are base as it existed before the priority date of that claim :
(i) is novel ; and
(ii) involves and innovative step; and
(c) is useful; and
(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

Certain inventions not patentable inventions for the purposes of an innovation patent

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a mocrobiological process or a product of such a process.

III. BRAZIL :

The Patents Act of Brazil (1996) provides for patentable inventions as follows :

Patentable Inventions and Utility Models :

Article 8. An invention shall be patentable if it meets the requirements of novelty, inventive step and industrial application.

Article 11. An invention or utility model shall be considered to be new if it does not form part of the state of the art.

(1) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing date of the patent application in Brazil or elsewhere, except as provided in Articles 12, 16 and 17.

(2). For the purpose of determining novelty, the whole contents of an application filed in Brazil, but not yet published, shall be considered as comprised in the state of the art as from the date of filing or of claimed priority, once published, even if subsequently.

(3) The provisions of the proceeding paragraph shall apply to an international patent application filed in accordance with a treaty or convention in force in Brazil, provided that there is national processing.

Article 13 : An invention shall be considered as involving inventive step if, having regard to the state of the art, it is not evident or obvious to a person skilled in the art.

Article 15 : Inventions and utility models shall be considered as susceptible of industrial application if they can be used or made in any kind of industry.

IV. CANADA :

Article 2.Definitions. – In this Act, except as otherwise provided,

"invention".- "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter ;

V. CHINA

The Patents Act of China (1992) provides for patentability of invention

Article 22. Any invention or utility model for which patent right may be granted must posses novelty, inventiveness and practical applicability.

Novelty means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications in the country or abroad or has been publicly used or made known to the public by any other means in the country, nor has any other person filed previously with the Patent Office an application which described the identical invention or utility model and was published after the said date of filing.

Inventiveness means that, as compared with the technology existing before the date of filing the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress.

Practical applicability means that the invention or utility model can be made or used and can produce effective results.

VI. CHILE :

The Patents Act of Chile (1991) deals with the patentable subject matter as follows :

Article 31. The word "invention" shall mean any solution to a technical problem arising in an industrial concern. An invention may be or may relate to a product or a process.

The word "patent" shall mean the exclusive right granted by the State for the protection of an invention. The effects, obligations and limitations embodied in the patent shall be determined by this Law.

Article 32. An invention shall be patentable where it is new, involves and inventive step and is susceptible of industrial application.

Article 33. An invention shall be considered new if it does not already form part of the state of the art. The state of the art shall be held to comprise everything disclosed or made available to the public anywhere in the world by publication in tangible form, sale or marketing or use, or in any other manner, before the date of filing of the patent application in Chile. The subject matter of a patent application that has been filed with the Department prior to the date of the application being examined shall also be regarded as forming part of the state of the art.

Article 35. An invention shall be regarded as involving an inventive step if it is neither obvious to a person of average skill in the art nor obviously derived from the state of the art.

Article 36. An invention shall be considered susceptible of industrial application if it can, in principle, be made or used in any kind of industry. For such purposes, the word "industry" shall be understood in its broadest sense, including activities such as manufacturing, mining, building, crafts, agriculture, forestry and fishing.

VII. FRANCE :

The Patents Act of France (1996) provides for patentable invention as follows :

Patentable Inventions :

Article L.611.10-1. Inventions which are susceptible of industrial application, which are new and which involve an inventive step shall be patentable.

2. The following in particular shall not be regarded as inventions within the meaning of paragraph 1 of this Article :

(a) discoveries, scientific theories and mathematical methods ;
(b) aesthetic creations ;
(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers ;
(d) presentations of information.

3. The provisions of paragraph 2 of this Article shall exclude patentability of the subject matter or activities referred to in that provision only to the extent to which a patent application or patent relates to such subject matter of activities as such.

Article L.611-11. An invention shall be considered to be new if it does not form part of the state of the art.

The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use or in any other way, before the date of filing of the patent application.

Additionally, the content of French patent applications and of European or international patent applications which designate France as filed, of which the dates of filing are prior to the date referred to in the second paragraph of this Article and which were published on or after that date, shall be considered as comprised in the state of the art.

The provisions of the foregoing paragraphs shall not exclude the patentability of any substance or composition, comprised in the sate of the art, for use in a method referred to in Article L.611-16, provided that its use for any method referred to in that Article is not comprised in the state of the art.

Article L.611-14. An invention shall be considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the sate of the art also includes documents referred to in the third paragraph of Article L.611011, such documents shall not be considered in deciding whether there has been an inventive step.

Article L.611-15. An invention shall be considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

VIII. INDONESIA

The Patents Act of Indonesia (2001) deals with patentability as follows :

Article 1(2) : Invention shall mean an Inventor's idea that is poured in any activity of solving a specific problem in the field of technology, either in the form of a product or process, or an improvement and development of a product or a process.

Article 2(1) : A Patent shall be granted to an Invention, which is novel, involves inventive steps and is capable of industrial application.

Article 2 (2) : An invention involves inventive steps if said invention does not constitute something that is obvious to a person who possesses average technical skills.

Article 2(3) : The evaluation of whether or not an invention constitutes something that is obvious must be made taking into account the state of the art at the time the Application is filed or which has existed at the time the first Application was filed, in the case the Application is filed on the basis of a Priority Right.

Article 3 (1) : An invention is deemed to be novel if at the date of filing of the Application said invention is not the same with any previous technological disclosure.

IX. ISRAEL :

The Patents Act of Israel (1998) deals with patentability as follows :

What constitutes a patentable inventions :

Section 3. An invention whether a product or a process, which is new and useful, can be used in industry or agriculture, and which involves an inventive step, is a patentable invention.

What is new Invention :

Section 4. An invention is deemed new if it was not published, in Israel or abroad, before the application date :-

(1) by written, visual, audible or any other description, in a manner that enables a skilled person to make it according to the particulars of the description ;
(2) by exploitation or exhibition, in a manner that enables a skilled person to make it according to the particulars thus made known.

What is an inventive step :

Section 5. An inventive step is a step which does not, to an average skilled person, appear obvious in the light of information published before the application date in ways said in Section 4

Section 8. A patent shall be granted for a single invention.

X. JAPAN :

CHAPTER II
PATENTS AND APPLICATIONS FOR PATENTS

Patentability of Inventions

29.-(1) Any person who has made an invention which is industrially applicable may obtain a patent therefore, except in the case of the following inventions :

(i) inventions which were publicly known in Japan or elsewhere prior to the filing of the patent applications ;

(ii) inventions which were publicly worked in Japan or elsewhere prior to the filing of the patent applications ;

(iii) inventions which were described in a distributed publication or made available to the public through electric telecommunication lines in Japan or elsewhere prior to the filing of the patent application.

(2) Where an invention could easily have been made, prior to the filing of the patent application, by a person with ordinary skill in the art to which the invention pertains, on the basis of an invention or inventions referred to in any of the paragraphs of Subsection (1), a patent shall not be granted for such an invention notwithstanding Subsection (1).

29 *bis*. Where an invention claimed in a patent application is identical with an invention or device (excluding an invention or device made by the same person as the inventor of thye invention claimed in the patent application) disclosed in the specification or drawings originally attached to the request of another application for a patent (in the case of a foreign language file application referred to in Section 36 *bis* (2) of this Law, the foreign language file referred to in Section 36*bis* (1) of the said Law) or of an application for a utility model registration which was filed prior to the filing date of the patent application and for which the Patent Gazette which states the matter referred to in each paragraph of Section 66(3) of the said Law (hereinafter referred to as "the Gazette containing the Patent") was published under the said subsection or the laying open for public inspection (Kokai) was effected or the Utility Model Gazette which states the matter referred to in each paragraph of Section 14(3) of Utility Model Law (No. 123 of 1959) (hereinafter referred to as "the Gazette containing the Utility Model") was published under the said subsection after the filing of the patent application, a patent shall not be granted for the invention notwithstanding Section 29(1). However, this provision shall not apply where, at the time of filing of the patent application, the applicant of the patent application and the applicant of the other application for a patent or the application for a utility model registration are the same person.

Exceptions to Lack of Novelty of Invention

30.-(1) In the case of an invention which has fallen under any of the paragraphs of Section 29(1) by reason of the fact that the person having the right to obtain a patent has conducted an experiment, has made a presentation of printed publication, has made a presentation through electric telecommunication lines, or has made a presentation in writing at a study meeting held by a scientific body designated by the Commissioner of the Patent Office, such invention shall be deemed not have fallen under any of the paragraphs of Section 29(1) for the purposes of Section 29(1) and (2) to the invention claimed in the patent application which has been filed by such person within six months from the date on which the invention first fell under those paragraphs.

(3) In the case of an invention which has fallen under any of the paragraphs of Section 29(1) against the will of the person having the right to obtain a patent, the preceding subsection

shall also apply fo9r the purposes of Section 29(1) and (2) to the invention claimed in the patent application which has been filed by such person within six months from the date on which the invention first fell under any of those paragraphs.

4. In the case of an invention which has fallen under any of the paragraphs of Section 29(1) by reason of the fact that the person having the right to obtain a patent has exhibited the invention at an exhibition held by the Government or by any local public entity (hereinafter referred to as the "Government, etc.") or at one which is not held by the Government, etc. but is designated by the Commissioner of the Patent Office, or at an international exhibition held in the territory of a country party to the Paris Convention or of a Member of the World Trade Organization by its government, etc. or by a person authorized thereby, or at an international exhibition held in the territory of a country not party to the Paris Convention not a member of the World Trade Organization by its government, etc. or by a person authorized thereby where such exhibition has been designated by the Commissioner of the Patent Office, Subsection (1) shall also apply for the purposes of Section 29(1) and (2) to the invention claimed in the patent application which has been filed by such person within six months form the date on which the invention first fell under those paragraphs.

(4) Any person who desires the application of Subsection (1) or the preceding subsection shall submit a written statement to that effect to the Commissioner of the Patent Office simultaneously with the patent application and within 30 days of the filing of the patent application, he shall also submit to the Commissioner of the Patent Office a document proving that the invention that has fallen under any of the paragraphs or Section 29(1) is the invention for which the provision of Subsection (1) or the preceding subsection may be applicable.

Unpatentable Inventions

32. The inventions liable to contravene public order, morality or public health shall not be patented, notwithstanding Section 29.

XI. PAKISTAN :

PATENTABILITY

7. Patentable inventions :

1. Any invention is patentable, if it is new, involves and inventive step and is Capable of industrial application.

2. Subject to sub-section (2), the following shall not be regarded as invention Within the meaning of sub-section (1), namely :

   a. a discovery, scientific theory or mathematical method ;
   b. a literary, dramatic, musical or artistic work or any other creation of purely aesthetic character whatsoever ;

c. a scheme, rule or method for performing a mental act, playing a game or doing business ;
d. the presentation of information ; and
e. substances that exist in nature or if isolated therefrom.

3. The provisions of sub-section (2) shall prevent anything from being treated as an invention for the purposes of this Ordinance only to the extent that a patent or an application for a patent relates to that thing as such.

4. A patent shall not be granted

a. for invention the prevention of commercial exploitation of which would be necessary to protect the "order public" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by any law for the time being in force ;

b. for plants and animals other than micro-organisms, and essentially biological process for the production of plants or animals other than non-biological and microbiological processes ;

c. for diagnostic, therapeutic and surgical methods for the treatment of humans or animals ;

d. for a new or subsequent use of a known product or process ; and

e. for a mere change in physical appearance of a chemical product where the chemical formula or process of manufacture remains the same provided that this clause shall not apply to an invention fulfilling the criteria of patent ability.

8. Novelty :

1. An invention shall be considered to be new if it does not form part of the state of the art.

2. The state of the art shall comprise

a. everything disclosed to the public anywhere in the world, by publication in tangible form or by oral disclosure, by use or in any other way, prior to the filing or, where appropriate, the priority date, of the application claiming the invention ; or

b. contents of the complete specification and priority documents published under section 21 of an application filed in Pakistan ;

c. traditionally developed or existing knowledge available or in possession of a local or indigenous community.

XII. THAILAND :

The Patents Act of Thailand (1999) defines patentability as follows :

Section 3(2) : invention means any innovation or invention which creates a new product or process, or any improvement of a known product or process;

process means any method, art of process of producing, maintaining or improving the quality of a product, including the application of such process;

Subject to Section 9 a patent may be granted only for an invention in respect of which the following conditions are satisfied :

Section 5 : (1) the invention is new ;
(2) it involves an inventive step ; and
(3) it is capable of industrial application.

Section 6: An invention is new if it does not form part of the state of the art.

The state of art also includes any of the following inventions :
(1) an invention which was widely known or used by others in the country before the date of application for the patent ;

(2) an invention the subject matter of which was described in a document or printed publication, displayed or otherwise disclosed to the public, in this or a foreign country before the date of the application for a patent ;

(3) an invention for which a patent or petty patent was granted in this or a foreign country before the date of application ;

(4) an invention for which a patent or petty patent was applied in a foreign country more than eighteen months before the date of the application and a patent or petty patent has not been granted for such invention ;

(5) an invention for which a patent or petty patent was applied for in this or a foreign country and the application was published before the date of application.

A disclosure which was due to, or made in consequence of, the subject matter having been obtained unlawfully, or a disclosure which was made by the inventor, or made in consequence of, the inventor displaying the invention at an international exhibition or an official exhibition if such disclosure was done within twelve months before the filing of an application for the patent, shall not be deemed to be a disclosure under subsection (2) above.

Section 7 : An invention shall be taken to involve an inventive step if it is not obvious to a person ordinary skilled in the art.

Section 8 : An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including handicrafts, agriculture and commerce.

XIII. UNITED KINGDOM :

The Patents Act of UK (1977 defines that patentability will be as follows :

Patentable Inventions :

Section 1.-(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say-

(a) the invention is new ;
(b) it involves an inventive step ;
(c) it is capable of industrial application ;
(d) the grant of a patent for it is not excluded by subsections (2) and (3) below

and reference in this Act to a patentable invention shall be construed accordingly.

Novelty :

Section 2-(1) An invention shall be taken to be new if it does not form part of the sate of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, but use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention. If the following conditions are satisfied, that is to say –

(a) that matter was contained in the application for that other patent both as filed and as published ; and

(b) the priority date of that matter is earlier than that of the invention.

Inventive Step :

Section 3. An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3)

Industrial application :

Section 4 -(1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

XIV. INDIA :

Compared to the provision on scope of patentability in other countries, the amended Patents Act 1970 of India provides as follows for the same :

Section 2 : Definitions and interpretation :

(ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry ;

(j) " invention" means a new product or process involving an inventive step and capable of industrial application ;

(l) Proposed to be omitted in Draft Patent (Amendment) Bill 2003

Section 3 : What are not inventions :

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals ;

This would mean that micro-organism will be patentable even when there is no decision yet on mandated review by WTO of Article 27(3)(b) of TRIPS dealing with patenting of micro-organisms.

Section 5 :

Proposed to be omitted in Draft Patents (Amendment) Bill 2003

Analysis of above provisions would indicate that on scope of patentability the amended Act will have totally inadequate provisions. There is no provision defining novelty/new invention, state of art and patentable subject matter. There is also no definition of patentable pharmaceutical as.recommended by Mashelkar Committee.

The definition of invention is also quite open whereas it should be for 'basic novel invention'. The 'scope of patentability' is an important patent component and as such should be carefully provided as has been done by other committee.

PART B

COMPULSORY LICENCE FOR COMMERCIAL ACTIVITY

Relevant extracts from Patent Laws of Argentina, Brazil, Canada, China, France, Germany, Indonesia, Israel, Thailand and United Kingdom are reproduced as follows :

I. ARGENTINA :

For commercial activity the Patents Act of Argentina (1996) provides as follows :

Other uses not requiring authorization by the owner of the Patent :

Article 42. Where a prospective user has attempted to secure the grant of a licence from the owner of a patent on reasonable commercial terms and conditions under Article 43, and the attempts have had no effect after 150 days have elapsed following the date on which the licence in question was requested, the National Institute of Industrial Property may allow other uses of the said patent without authorization by the owner, thereof. Without prejudice to the foregoing, notice shall be given to the authorities created by Law No. 22.262, or such law as may amend or replace it, on the protection of free competition, for whatever purposes may be appropriate.

Article 43. If, after three months have elapsed since the grant of the patent, or four since the filing of the application, the invention has not been exploited, except in cases of force majeure, or if no genuine and effective preparations have been made for such exploitation, or where such exploitation has been interrupted for more than a year, any person may apply for authorization to use the invention without seeking the permission of the owner thereof.

II. BRAZIL :

The Patents Act of Brazil (1996) provides for grant of Compulsory Licences for commercial purposes :

Article 61. A patent owner or applicant may conclude a licensing contract.

Sole paragraph. The patent owner may afford to the licensee full powers to act in defense of the patent.

Article 64. A patent owner may request INPI to put up his patent for offer with a view to its exploitation.

(1) INPI shall publish the offer.

(2) No exclusive voluntary licence shall be recorded with INPI unless the patent owner has withdrawn his offer.

(3) No patent that is subject to an exclusive voluntary licence may be put up for offer.

(4) The patent owner may withdraw his offer at any time prior to express acceptance of the terms of the offer by an interested party, whereby the provisions of Article 66 shall not apply.

Article 73. An application for a compulsory licence shall be drawn up by setting out the conditions offered to the patent owner.

(1) On filing of the licence application, the patent owner shall be invited to submit his comments within a period of 60 days, on expiry of which, in the absence of a reply from the patent owner, the proposal shall be deemed accepted under the conditions offered.

III. CANADA :

The Patents Act of Canada (1996) provides for compulsory licence for commercial activity as follows :

19.1(1) : Conditions for authorizing use : The Commissioner may not authorize the use of a patented invention under Section 19 unless the applicant establishes that

(a) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention ; and

(b) its efforts have not been successful within a reasonable period.

Article 65 (2) What amounts to abuse – The exclusive rights under a patent shall be deemed to have been abused in any of the following cicuumstances :

(a) and (b) replaced in 1993.

(b) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms ;

(c) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted.

IV. CHINA :

The Patents Act 1992 of China provides for Compulsory Licence for Exploitation of the Patent as follows :

Article 51. Where any entity which is qualified to exploit the invention or utility model has made requests for authorization from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and such efforts have not been successful within a reasonable period of time, the Patent Office may, upon the application of that entity, grant a compulsory licence to exploit the patent for invention or utility model.

Article 57. The entity or individual that is granted a compulsory licence for exploitation shall pay to the patentee a reasonable exploitation fee, the amount of which shall be fixed by both parties in consultations. Where the parties fail to reach an agreement the Patent Office shall adjudicate.

V. FRANCE :

The Patents Act of France (1996) provides for grant of ex-officio licences as follows :

Article L.613.16. Where the interests of public health demand, patents granted for medicines for processes for obtaining medicines, for obtaining medicines, for products necessary in obtaining such medicines or for process for manufacturing such products may be subject to ex officio licences in accordance with Article L 613-17 in the event of such medicines being made available to the public in sufficient quantity or quality or at abnormally high prices by order of the Minister responsible for industrial property at the request of the Minister responsible for health.

Article L.613.17. As from the date of publication of the order subjecting the patent ex officio licences, any qualified person may apply to the Minister responsible for industrial property for the grant of a licence to work the patent. The licence shall be granted by order of that Minister under fixed conditions, particularly in respect of its duration and field of application, but excluding the amount of the royalties to be paid in consideration thereof.

The licence shall take effect from the date of notification of the order to the parties.

In the absence of amicable agreement approved by the Minister responsible for industrial property and the Minister responsible for health, the amount of the royalties shall be laid down by the First Instance Court.

VI. GERMANY :

The Patents Act of Germany (1999) provides for grant of compulsory licence for commercial purposes as follows :

Section – 24(1) : If the applicant or patentee refuses to permit the exploitation of the invention by another person offering to pay reasonable compensation and to furnish security therefore, such person shall be given authority to exploit the invention (compulsory licence) where permission is in the public interest. The grant of a compulsory licence shall be permissible only after the grant of the patent. A compulsory licence may be granted subject to restrictions and made dependent upon conditions.

VII. INDONESIA :

The Patents Act of Indonesia (2001) provides for grant of compulsory licence for commercial purposes as follows :

Article 76 : (1) In addition to the truth of grounds as referred to in Article 75 Paragraph (2), a Compulsory Licence may only be granted if :

a. the person filing the request can provide convincing evidence that he :

   1. has the ability to personally and fully implement the relevant Patent :
   2. has his own facilities to readily implement the relevant Patent ;
   3. has made efforts in a sufficient period of time to acquire a Licence from the Patent Holder on the basis on normal terms and conditions but did not succeed,

b. the Directorate General is of the opinion that relevant Patent can be implemented in Indonesia on a feasible economic scale and can be of benefit the majority of the society.

(2) The examination of a request for a compulsory licence shall be carried out by the Directorate General by hearing the opinion of other related government agencies and parties, as well as the relevant Patent Holder.

(3) A Compulsory Licence shall be granted for a period no longer than the period of Patent protection.

VIII. ISRAEL :

The Patents Act of Israel (1998) provides about the power to grant compulsory licence as follows :

Power to grant compulsory licence.

Section 117 (a) If the Registrar is satisfied that a patent holder abuses his monopoly, then he may grant a licence to exploit the invention that is the subject of the patent to a person who applied therefor in the prescribed manner and paid the prescribed fee.

Power to require notification concerning exploitation of patent :

Section 118 (a) : At the end of the time said in section 117, the Registrar may demand that a patent holder notify him, within sixty days of the date of the demand, whether he exploits the patented invention in Israel by way of production, and if so, what the extent and the location of the production are.

Abuse of monopoly defined :

Section 119 : The exercise of a monopoly conferred by a patent shall be deemed abusive, if one othe following circumstances exists in respect of the invention, the product or the process which is the subject of the patent, and if the patent holder did not provide a reasonable justification for its existence :

(1) all the demand for the product is not satisfied in Israel on reasonable terms ;

(2) the conditions attached by the patent holder to the supply of the product or to the grant of a licence for its production or use are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent ;

(3) exploitation of the invention by way of production in Israel is impossible or restricted by the importation of the product ;

(4) the product is not produced in Israel and the patent holder refuses to grant to a local producer a licence for its production or use on reasonable terms, neither for the requirements of the local market nor for export purposes ;

(5) the patent holder refuses to grant a licence for the production of the product or for the use of the process in Israel on reasonable terms and because of that refusal:
(a) the export of a product from Israel is prevented or adversely affected; or
(b) the launching or development in Israel of a commercial or industrial activity is prevented.

IX. THAILAND :

The Patents Act of Thailand (1999) provides for grant of compulsory licence for commercial purposes as follows :

Section 38 : The patentee may authorize any other person, by granting a licence, to exercise the rights conferred to him under Section 36 and 37, and may assign his patent to any other person.

Section 39 : In granting a licence under Section 38,
(1) the patentee shall not impose upon the licensee any condition, restriction or any royalty term which is unjustifiably anti-competitive.

Conditions,restrictions or terms which is unjustifiably anti-competitive shall be prescribed in the Ministerial Regulations ;

(2) the patentee shall not require the licensee to pay royalties for the use of the patented invention after the patent has expired in accordance with Section 35.
Conditions, restrictions or terms concerning royalties which are contrary to the provision of the Section are null and void.

Section 45 : Any patentee may, in accordance with the rules and procedures as prescribed in the Ministerial Regulations, apply to the Director-General for an entry to be made in the register to the effect that any other person may obtain a license.

At any time after an entry has been made, the Director-General shall grant a licence under the patent to any person who applies for such a licence on such conditions, restrictions and royalty terms as agreed upon by the patentee and the applicant. If the patentee and the applicant cannot agree within the period as prescribed by the Director-General, the Director-

General shall grant a licence on such conditions, restrictions and royalty terms as he deem appropriate.

Section 46 : At any time after the expiration of three years from the grant of a patent of four years from the date of application, whichever is later, any person may apply to the Director-General for a licence if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows :

(1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reasons ; or

(2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

Whether it is an application under (1) or (2), the applicant for a licence must show that he had made an effort to obtain a licence from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

X. UNITED KINGDOM :

The Patents and Trade Marks (WTO) Regulation 1999 provides for grant of Compulsory licences for commercial purposes as follows :

Section 48-(1) : At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the comptroller on one or more of the grounds :

(a) for a licence under the patent

(b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right, or

(c) where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent.

Compulsory licences : WTO proprietors :

Section 48 (A) (2) : No order or entry shall be made under section 48 above in respect of a patent whose proprietor is a WTO proprietor unless –

(a) the application has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions ; and
(b) his efforts have not been successful within a reasonable period.

XI. INDIA :

The above analysis of the Patents Acts would indicate that the several countries have been quite careful in providing for compulsory licence for commercial activity. As compared this the amended Patents Act 1970 of India has totally ignored providing of this important provision which is based upon Article 31 of the TRIPS Agreement. The relevant extracts of the Article are reproduced as follows :

Article 31 (b) of TRIPS Agreement)

"(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."

The new Bill should provide for this provision on the lines as other countries have provided.

PART C

Pre-grant Opposition on Patent Claims

In order to retain the existing provision on 'pre-grant opposition' in the Patents Act 1970 of India, similarly provision in the Patents Acts of other countries is reproduced herewith. These countries are : Argentine, Australia, Brazil, Canada, China, France, Israel, Indonesia, Japan, New Zealand, Pakistan, Thailand and United Kingdom.

I. ARGENTINA :

Article 26 : The National Patent Administration shall proceed with the publication of the pending patent application within 18 months following the filing date thereof. At the request of the applicant, the application shall be published before the said period expires.

Article 28 : Any person may make reasoned comments on the patent application and add documentary proof within a period of 60 days following the publication provided for in Article 26. The comments shall consist of allegations of non-fulfillment or insufficient fulfillment of the legal requirements for the grant of a patent.

II. AUSTRALIA :

Section 59 : Opposition to grant of standard patent :

The Minister of any other person may, in accordance with the regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground :

(a) that the nominated person is either.
(i) not entitled to a grant of a patent for the invention ; or
(ii) entitled to a grant of a patent for the invention but only in conjunction with some other person ;
(b) that the invention is not a patentable invention;
(c) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3)

Section 60 : Hearing and decision by Commissioner

(1) Where the grant of a standard patent is opposed, the Commissioner must decide the case in accordance with the regulations.

(2) The Commissioner must give the applicant and the opponent a reasonable opportunity to be heard before deciding a case.

(3) The Commissioner may, in deciding a case, take into account any ground on which the grant of a standard patent may be opposed, whether relied upon by the opponent or not.

(4) The applicant, and any opponent, may appeal to the Federal Court against a decision of the Commissioner under this section.

Section 101M : Opposition to innovation patent :

The Minister, or any other person, may, in accordance with the regulations, oppose an innovation patent that has been certified and seek the revocation of it, on one or more of the following grounds of invalidity, but on no other :

(a) that the patentee is either.
(i) not entitled to the patent ; or
(ii) entitled to the patent but only in conjunction with some other person ;
(b) that the invention is not a patentable invention because it does not comply with paragraph 18(1A) or (b) ;
(c) that the inventionis not a patentable invention under subsection 18(2) or (3) ;
(d) that the complete specification does not comply with subsection 40(2) or (3).

III. BRAZIL :

Article 51 : Proceedings for nullity may be instituted ex officio or at the request of any person having a legitimate interest within six months as from grant of the patent.

Sole paragraph. Proceedings for nullity shall continue even if the patent has lapsed.

Article 52 : The patent owner shall be invited to make his comments within a period of 60 days.

Article 53 : Irrespective of the filing of comments, once the period of time laid down in the preceding Article has expired, INPI shall issue an opinion and shall invite the patent owner and the applicant to submit comments within a common period of 60 days.

Article 54 : On expiry of the time limit laid down in the preceding Article even if no comments have been received, the matter shall be decided by the President of INPI and the administrative procedure shall be terminated.

IV. CANADA :

Re-examination

Section 48.1 (1) : Request for re-examination – Any person may request a re-examination of any claim of a patent by filing with the Commissioner prior art, consisting of patents, applications for patents open to public inspection and printed publications, and by paying a prescribed fee.

(2) Pertinency of request.- A request for re-examination under subsection (1) shall set forth the pertinency of the prior art and the manner of applying the prior art to the claim for which re-examination is requested.

(3) Notice to patentee.- Forthwith after receipt of a request for re-examination under subsection (1), the Commissioner shall send a copy of the request to the patentee of the patent

in respect of which the request is made, unless the patentee is the person who made the request. R.S.C.1985, c33 (3rd Supp.), s.18:S.C.1993, c.15,s.45.

Section 48.2 (1) : Establishment of re-examination board.- Forthwith after receipt of a request for re-examination under subsection 48.(1), the Commissioner shall establish a re-examination board consisting of not fewer than three persons, at least two of whom shall be employees of the Patent Office, to which the request shall be referred for determination.

(2) Determination to be made by board.- A re-examination board shall, within three months following its establishment, determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request for re-examination.

(3) Notice- Where a re-examination board has determined that a request for re-examination does not raise a substantial new question affecting the patentability of a claim of the patent concerned, the board shall so notify the person who filed the request and the decision of the board is final for all purposes and is not subject to appeal or to review by any court.

(4) Idem.- Where a re-examination board has determined that a request for re-examination raises a substantial new question affecting the patentability of a claim of the patent concerned, the board shall notify the patentee of the determination and the reasons thereof.

(5) Filing of reply.- A patentee who receives notice under subsection (4) may, within three months of the date of the notice, submit to the re-examination board a reply to the notice setting out submissions on the question for the patentability of the claim of the patent in respect of which the notice was given. R.S.C.1985,c.33(3rd Supp.),s.18.

Section 48.3 (1) : Re-examination proceeding.- On receipt of a reply under subsection 48.2.(5) or in the absence of any reply within three months after notice is given under subsection 48.2(4), a re-examination board shall forthwith cause a re-examination to be made of the claim of the patent in respect of which the request for re-examination was submitted.

(2) Patentee may submit amendments. - In any re-examination proceeding under subsection (1), the patentee may propose any amendment to the patent or any new claims in relation thereto but no proposed amendment or new claim enlarging the scope of a claim of the patent shall be permitted.

(3) Time limitation.- A re-examination proceeding in respect of a claim of a patent shall be completed within twelve months of the commencement of the proceedings under subsection (1). R.S.C. 1985,c.33(3rd Supp.), s.18.

Section 48.4 (1) : Certificate of board. – On conclusion of a re-examination proceeding in respect of a claim of a patent, the re-examination board shall issue a certificate

(a) canceling any claim of the patent determined to be unpatentable ;
(b) confirming any claim of the patent determined to be patentable ; or
(c) incorporating in the patent any proposed amended or new claim determined to be patentable.

(2) Certificate attached to patent.- A certificate issued in respect of a patent under subsection (1) shall be attached to the patent and made part thereof by reference, and a copy of the certificate shall be sent by registered mail to the patentee.

(3) Effect of certificate. – For the purpose of this Act, where a certificate issued in respect of a patent under subsection (1)

(a) cancels any claim but not all claims of the patent, the patent shall be deemed to have been issued, from the date of grant, in the corrected form ;
(b) cancels all claims of the patent, the patent shall be deemed never to have been issued ; or
(c) amends any claim of the patent or incorporates a new claim in the patent, the amended claim or new claim shall be effective, from the date of the certificate, for the unexpired term of the patent.

(4) Appeals.- Subsection (3) does not apply until the time for taking an appeal has expired under subsection 48.5(2) and, if an appeal is taken, subsection (3) applies only to the extent provided in the final judgement on the appeal. R.S.C.1985,c.33(3rd Supp),s.18;S.C.1993,c.15.s.47.

Section 48.5 (1) : Appeals.- Any decision of a re-examination board set out in a certificate issued under subsection 48.4(1) is subject to appeal by the patentee to the Federal Court.

(2) Limitation.- No appeal may be taken under subsection (1) after three months from the date a copy of the certificate is sent by registered mail to the patentee. R.S.C.1985,c.33 (3rd Supp), s.18.

V. CHINA

Article 40 : Where it is found after preliminary examination that there is no cause for rejection of the application for a patent for utility model or design, the Patent Office shall make a decision to grant the patent right for utility model or the patent right for design, issue the relevant patent certificate, and register and announce it.

Article 41 : Where, within six months from the date of the announcement of the grant of the patent right by the Patent Office, any entity or individual considers that the grant of the said patent right is not in conformity with the relevant provisions of this law, it or he may request the Patent Office to revoke the patent right.

Article 42 : The Patent Office shall examine the request for revocation of the patent right, make a decision revoking or upholding the patent right, and notify the person who made the request and the patentee. The decision revoking the patent right shall be registered and announced by the Patent Office.

Article 43 : The Patent Office shall set up a Patent Reexamination Board. Where any party is not satisfied with the decision of the Patent Office rejecting the application, or the decision of the Patent Office revoking or upholding the patent right, such party may, within three

months from the date of receipt of the notification, request the Patent Reexamination Board to make a reexamination. The Patent Reexamination Board shall, after reexamination, make a decision and notify the applicant, the patentee or the person who made the request for revocation of the patent right.

Where the applicant for a patent for invention, the patentee of an invention or the person who made the request for revocation of the patent right for invention is not satisfied with the decision of the Patent Reexamination Board, he or it may, within three months from the date of receipt of the notification, institute legal proceedings in the people's court.

The decision of the Patent Reexamination Board is respect of any request, made by the applicant, the patentee or the person who made the request for revocation of the patent right, for reexamination concerning a utility model or design is final.

Article 44 : Any patent right which has been revoked shall be deemed to be non-existent from the beginning.

VI. FRANCE :

Article L.612-13. : As from the day the application is filed and up to the day on which the documentary search prior to the report referred to in Article L.612-14 has been commenced, the applicant may file new claims.

The possibility of filing new claims shall be open to the applicant for a utility certificate up to the day the title is granted.

As from the day the patent application is published under item 1 of Article L.612-21 and within a period of time to be laid down by regulation, any third party may address to the National Institute of Industrial Property written comments on the patentability, within the meaning of Articles L.611-11 and L.611-14, of the invention which is the subject of the application. The National Institute of Industrial Property shall communicate such comments to the applicant who, within a period of time laid down by regulation, may submit comments in reply and file new claims.

VII. ISRAEL :

Article Three : Opposition to Grant of Patent :

Time for opposition to grant of patent :

30. Any person may – within three months after the date of publication of the application under section 26 – oppose the grant of a patent by written notice to the Registrar.

Grounds for opposition :

31. The following are the grounds for opposition to the grant of a patent :

(1) there is a reason, because of which the Registrar could have refused to accept the patent application ;
(2) the invention is not patentable under section 4(2) :
(3) the opponent, and not the applicant, is the owner of the invention.

Powers of Registrar in opposition proceeding :

32. (a) The Registrar may accept all or part of the opposition, he may reject it or he may exercise his powers under section 18,23 and 24 in respect of the application.

(b) If the Registrar demanded that the application be divided, then he shall not publish The separated applications under section 26.

Powers of Registrar after cancellation of opposition :

33. (a) If the opposition was submitted for grounds said in section 31(3), then the opponent may request that the patent be granted to him, and the Registrar may – in addition to any other relief – grant the patent to the person who proved that he is the owner of the invention.

(b) In proceedings under this section the Registrar may join any person whom the Registrar believes to have an interest in the matter.

Powers of Registrar after cancellation of opposition :

34. If opposition was duly submitted under section 30 and was subsequently cancelled, then Registrar may refuse to grant the patent applied for it, in the course of the opposition, he discovered material according to which the application should not have been accepted in the first place.

VII. INDONESIA :

Article 45 : (1) Any person may see the announcement as referred to in Article 44 and may file in writing his comment and/or objection on an Application by stating the reasons therefore.

(2) Where there is any comment or objection as referred to in Paragraph (1), the Directorate General shall immediately send a copy of the letter containing the comment and/or objection to the Applicant.

(3) The Applicant shall have the right to submit to the Directorate General a written denial and explanations with respect to such a comment and/or objection.

(4) The Directorate General shall use the comments and/or objections, denials and/or explanations as referred to in Paragraph (1) and Paragraph (2) as additional information for consideration during the substantive examination.

Article 53 : If following the notification as referred to in Article 52 Paragraph (1) the Applicant does not provide any clarification or complete the deficiencies, or does not make any changes or improvement on the Application within the period stipulated by the Directorate General as referred to in Article 51 Paragraph (2), the relevant Application shall be deemed withdrawn and the Directorate General shall notify the Applicant in writing.

VIII. JAPAN :

Section 113. – Only within six months from the publication of the Gazette containing the patent, any person may file with the Commissioner of the Patent Office an opposition to the patent on the grounds that the patent falls under any of the under mentioned paragraphs. In this context, if there are two or more claims, the opposition may be filed for each claim. That is : (i) where the patent has been granted on a patent application (excluding any foreigh language file application) with an amendment which does not comply with the requirements of

Section 17 bis (3) :

(ii) where the patent has been granted contrary to Section 25,29, 29bis, 32 or 39 (1) to (4) ;

(iii) where the patent has been granted contrary to the provisions of a treaty ;

(iv) where the patent has been granted on a patent application which does not comply with the requirements of Section 36(4) or (6) [excluding Paragraph (iv)] ;

(v) where the features disclosed in the specification or drawings attached to a request with respect to the patent under a foreign language file application do not remain within the scope of the features disclosed in the foreign language file.

(Ruling)

Section 114 – (1) A trial concerning an opposition and ruling thereon shall be conducted by a collegial body of three or five trial examiners.

(2) Where it is found that a patent concerned in the opposition falls under any of the paragraphs in the preceding section, the trial examiners shall render a ruling that the patent is to be revoked (hereinafter referred to as "ruling to revoke")

(3) Where a ruling to revoke has become final and conclusive, the patent right shall be deemed never to have existed.

(4) Where it is not found that a patent concerned in the opposition falls under any of the paragraphs in the preceding section, the trial examiners shall render a ruling that the patent is to be maintained.

(5) No appeal shall lie from a ruling under Subsection (4).

(Formal requirements of a written opposition, etc.)

Section 115- (1) A person filing an opposition shall submit a written opposition to the Commissioner of the Patent Office stating the following :

(i) the name of the domicile or residence of the opponent and his representative ;

(ii) an identification of the patent concerned in the opposition ;

(iii) the grounds of the opposition and an indication of the supporting evidence.

(2) An amendment of the written opposition submitted under the preceding subsection shall not change the gist thereof. However, this provision shall not apply to an amendment made to the matter prescribed in Paragraph (iii) of the preceding subsection before the expiration of the time limit prescribed in Section 113.

(3) The trial examiner-in-chief shall transmit a copy of the written opposition to the patentee.

(4) Section 123(3) shall apply mutatis mutandis where the opposition has been filed.

IX. NEW ZEALAND :

Section 21. Opposition to grant of patent :

(1) At any time within the period prescribed by subsection (2) of this section any person interested may give notice to the Commissioner of opposition to the grant of the patent on any of the following grounds :

(a) That the application for the patent, or the person described in the application as the true and first inventor, obtained the invention or any part thereof from him, or from a person of whom he is the personal representative.

(b) That the invention, so far as claimed in any claim of the complete specification, has been published in New Zealand before the priority date of the claim –

(i) In any specification filed in pursuance of an application for a patent made in New Zealand and dated within 50 years next before the date of filing of the applicant's complete specification :

(ii) In any other document (not being a document of any class described in subsection (1) of section 59 of this Act) :

(c) That the invention, so far as claimed in any claim of the complete specification, is claimed in any claim of a complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in New Zealand, being a claim of which the priority date is earlier than that of the applicant's claim ;

(d) That the invention, so far as claimed in any claim of the complete specification, was used in New Zealand before the priority date of that claim :

(e) That the invention, so far as claimed in any claim of the complete specification, is obvious and clearly does not involve any inventive step having regard to matter published as mentioned in paragraph (b) of this subsection, or having regard to what was used in New Zealand before the priority date of the applicant's claim :

(f) That the subject of any claim of the complete specification is not an invention within the meaning of this Art :

(g) That the complete specification does not sufficiently and fairly describe the invention or the method by which it is to be performed :

(h) That in the case of a convention application, the application was not made within 12 months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title :

(i) That, in the case of an application to which an order under section 37 of this Act applies, the failure of the applicant to comply with the requirements imposed on him by or under this Act within the period prescribed by section 19 of this Act and every extension of that period granted under that section or under section 93 of this Act was not unintentional :

(j) That in the case of an application to which an order under section 37 of this Act applies, there was undue delay in applying for the order :

(k) That, in the case of an application under section 93A of this Act, an extension of time granted by the Commissioner was unwarranted, - but on no other ground :

(2) Every such notice shall be given within 3 months from the date of the publication of the complete specification under this Act :
Provided that on application made to him in that behalf within the said 3 months the Commissioner may extend the prescribed period to 4 months.

(3) Where any such notice is given, the Commissioner shall give notice of the opposition to the applicant, and shall give to the applicant and the opponent an opportunity to be heard before he decides on the case :

(4) The grant of a patent shall not be refused on the ground specified in paragraph (c) of subsection (1) of this section if no patent has been granted in pursuance of the application mentioned in that paragraph : and for the purposes of paragraph (d) or paragraph (e) of the said subsection (1) no account shall be taken of any secret use.

(5) An appeal to the Court shall lie from any decision of the Commissioner under this section.

X. PAKISTAN :

OPPOSITION TO GRANT OF PATENT

23. Opposition to the grant of patent :

1. At any time within four months from the date of advertisement of the acceptance of a complete specification under this Ordinance, any person may give notice to the Controller of opposition to the grant of patent on any of the following grounds, namely :

   a. That the applicant for the patent obtained the invention or any part thereof from him or from the person of whom the opponent is the legal representative, assignee, agent or attorney ;

   b. That the invention is not a patentable ~~invention~~ within the meaning of this Ordinance;

   c. That the specification does not disclose the invention within the meaning of this Ordinance ;

   d. That the claims are not clear or extended beyond the scope of the disclosures in me complete specification as originally filed ; and

   e. That the complete specification describes or claims and invention other than that described in the provisional specification and that such other invention either forms the subject of an application made by the opponent for a patent which if granted would bear a date in the interval between the date of the application and the leaving of the complete specification, or has been made available to the public by publication in any document in that interval.

2. Where a notice is given under sub-section (2), the Controller shall give notice of the opposition to the applicant, and shall, before deciding the case, give to the applicant and the opponent an opportunity of being heard.

XI. THAILAND :

Section 31. Where an application for a patent has been published under Section 28, any person who thinks that he, not the applicant, is entitled to a patent, or that the application does not comply with the provisions of Section 5,9,10,11 or 14 may give notice to the competent officer of opposition to such application within ninety days following the publication of the application under Section 28.

Where an opposition has been made in accordance with the preceding paragraph, the competent officer shall send a copy of such notice to the applicant. The applicant shall file with the competent officer a counter statement within ninety days following the receipt of the copy of the notice. If the applicant fails to file such counter statement within said period, he shall be deemed to have abandoned his application.

A notice of opposition and counter statement shall be supported by buttressing evidence.

Section 32. In an opposition proceeding, the opposing party and the applicant may introduce any evidence or make any additional statement to support the ground on which they rely in accordance with the procedures prescribed by the Director General.

Where the Director General has made his decision under Section 33 or Section 34, the applicant and the opposing party shall be notified of the decision with the reasons on which it is based.

Section 34. Where there is an opposition and the Director-General has decided that the invention belongs to the opposing party, the Director-General shall reject the application.

Where the decision of the Director-General rejecting the application is not appealed by the applicant or is appealed and the Board or the Court has made a final decision, if the opposing party has filed an application for a patent within one hundred and eighty days after the rejection by the Director-General or from the date on which the final decision is made, as the case may be, he shall be deemed to have filed his application on the filing date of the applicant, and the publication of the application for a patent of the applicant made under Section 28 shall be deemed to be the publication of the application of the opposing party. In the later case, no person may oppose the application of the opposing party on the ground that he has better rights in the invention than the opposing party.

Before granting a patent to the opposing party, the competent officer shall examine the application is accordance with Section 24. The provisions of Section 29 are also applicable to the application of the opposing party.

XI. UNITED KINGDOM :

Section 8. – (1) : At any time before a patent has been granted for an invention (whether or not an application has been made for it) –

(a) any person may refer to the comptroller the question whether he is entitled to be granted (alone or with any other persons) a patent for that invention or has or would have any right in or under any patent so granted or any application for such a patent ; or

(b) any of two or more co-proprietors of an application for a patent for that invention may so refer the question whether any right in or under the application should be transferred or granted to any other person ; and the comptroller shall determine the question and may make such order as he thinks fit to give effect to the determination.

(2) Where a person refers a question relating to an invention under subsection (1)(a) above to the comptroller after an application for a patent for the invention has been filed and before a patent is granted in pursuance of the application, then unless the application is refused or withdrawn before the reference is disposed of by the comptroller, the comptroller may, without prejudice to the generally of subsection (1) above and subject to subsection (6) below :-

(a) order that the application shall proceed in the name of that person, either solely or jointly with that of any other applicant, instead of in the name of the applicant or any specified applicant ;

(b) where the reference was made by two or more persons, order that the application shall proceed in all their names jointly ;

(c) refuse to grant a patent in pursuance of the application or order the application to be amended so as to exclude any of the matter in respect of which the question was referred ;

(d) make an order transferring or granting any licence or other right in or under the application and give directions to any person for carrying out the provisions of any such order ;

(3) Where a question is referred to the comptroller under subsection (1)(a) above and -

(a) the comptroller orders an application for a patent for the invention to which the question relates to be so amended ;

(b) any such application is refused under subsection (2) (c) above before the comptroller has disposed of the reference (whether the reference was made before or after the publication of the application); or

(c) any such application is refused under any other provision of this Act or is withdrawn before the comptroller has disposed of the reference, but after the publication of the application ;

the comptroller may order that any person by whom the reference was made may within the prescribed period make a new application for a patent for the whole or part of any matter comprised in the earlier application or, as the case may be, for all or any of the matter excluded from the earlier application, subject in either case to section 76 below, and in either case that, if such a new application is made, it shall be treated as having been filed on the date of filing the earlier application.

(4) Where a person refers a question under subsection (1)(b) above relating to an application, any order under subsection (1) above may contain directions to any person for transferring or granting any right in or under the application.

(5) If any person to whom directions have been given under subsection (2)(d) or (4) above fails to do anything necessary for carrying out any such directions within 14 days after the date of the directions, the comptroller may, on application made to him by any person in whose favour or on whose reference the directions were given, authorize him to do that thing on behalf of the person to whom the directions were given.

(6) Where on a reference under this section it is alleged that, by virtue of any transaction, instrument or event relating to an invention or an application for a patent, any person other than the inventor or the applicant for the patent has become entitled to be granted (whether

alone or with any other persons) a patent for the invention or has or would have any right in or under any patent so granted or any application for any such patent, an order shall not be made under subsection (2)(a), (b) or (d) above on the reference unless notice of the reference is given to the applicant and any such person, except any of them who is a party to the reference.

(7) If it appears to the comptroller on a reference of a question under this section that the question involves matters which would more properly be determined by the court, he may decline to deal with it and, without prejudice to the court's jurisdiction to determine any such question and make a declaration, or any declaratory jurisdiction of the court in Scotland, the court shall have jurisdiction to do so.

(8) No direction shall be given under this section so as to affect the murual rights or obligations of trustees or of the personal representatives of deceased persons, or their rights or obligations as such.

(Determination after grant of questions referred before grant)

9. If a question with respect to a patent or application is referred by any person to the comptroller under section 8 above, whether before or after the making of an application for the patent, and is not determined before the time when the application is first in order for a grant of a patent in pursuance of the application, that fact shall not prevent the grant of a patent, but on its grant that person shall be treated as having referred to the comptroller under section 37 below any question mentioned in that section which the comptroller thinks appropriate.

XII. INDIA :

The existing provision in the Patents Act 1970 as amended by Patents (Second Amendment) Act 2002 is proposed to be diluted in the proposed new Bill. There is no requirement of TRIPS Agreement to do so. The proposed amendment is against out national interest and should not be stipulated at all.

NATIONAL WORKING GROUP ON PATENT LAWS
AND
PUBLIC INTEREST LEGAL SUPPORT AND RESEARCH CENTRE
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PRESS RELEASE

Sub: Fourth Peoples' Commission on Review of Patent Legislations amending Patents Act 1970.

1. This Press Release pertains to a critical issue of public importance which is going to affect the future of India and the welfare and health of the peoples of the world. Although seemingly concerned with technical changes in the time honoured Indian Patents Act, 1970, it deals with matters of fundamental importance.

2. Parliament has already enacted Patents (Amendment) Act, 1999, Patents (Second Amendment) Act, 2002 and the government has since introduced Patents (Amendment) Bill, 2003, in the Lok Sabha on 22nd December, 2003. By this legislative process according to government they have fulfilled their obligation to bring the Patents Act 1970 in conformity with the patent system as provided in the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. However, a preliminary examination of the three legislations, reveals that several important issues relevant to the patent system have been ignored in the amendment process. This is a cause of serious concern. The National Working Group on Patent Laws (NWGPL) and Public Interest Legal Support and Research Centre (PILSARC) have therefore been prompted to initiate a review of all the three legislations with the help of eminent persons.

3. In the past also eminent legal luminaries, economist, scientists and other experts in India have expressed through three Peoples' Commissions the need for a cautious and careful approach being adopted in regard to changing our national legislation on patent laws. The First Commission was established in 1993 on 'Constitutional Implications of the Final Act Embodying the results of the Uruguay Round of Multilateral Trade Negotiations'; the Second Commission established in 1998 looked into the obligations during the transitional period of TRIPS and the Third Commission on Patent Laws for India established in 2002 made a comprehensive study of the patent system and suggested crucial amendments within the frame work of binding commitments under the TRIPS Agreement. It is observed that in framing the draft legislations the government has ignored all important recommendations made by the three Commissions for reasons best known only to the government.

4. Internationally the Commission on Intellectual Property Rights established by the UK government in its Report of September, 2002, UNDP Report of 2003 on 'Making Global Trade Work for People and the Report of the Royal Society Working Group of 2003 on 'Keeping Science Open : Effect of IP Policy on Conduct of Science' have also cautioned about the need for a careful approach in implementing the TRIPS Agreement in the national legislations of the developing countries. The Doha Declaration on the TRIPS Agreement and Public Health of November 2001 has also clarified the flexibilities and freedom available to protect public health in developing countries. It has also recognized the gravity of public health problems afflicting many developing and least developed countries.

5. Keeping the above in view the NWGPL and PILSARC have decided to constitute a Fourth Peoples' Commission of eminent persons to review the three legislations keeping in view the Doha Declaration on the TRIPS Agreement and Public Health, Fundamental Rights guaranteed to our citizens in the Constitution of India, the implications of TRIPS in realization of economic, social and cultural rights as guaranteed by the International Human Rights Laws and cautious approach supported by various national and international commissions mentioned above. The Commission will also examine the issues which aught to be taken up the Government with the TRIPS Council.

6. Hon'ble Shri. I.K. Gujral former Prime Minister of India has agreed to chair this Commission. He was Chairman of a Parliamentary Committee which had warned of the social implications of patent in its Report on Dunkel Draft Text in 1993. He was also Chairman of the Third Peoples' Commission on Patent Laws for India which had studied in depth the relevant and crucial provisions to be incorporated in the Indian patent system.

7. The following eminent persons have been pleased to agree to sit, discuss and consider with an open mind the crucial issues involved relating to patent laws will constitute the Fourth Peoples' Commission on Review of Patent Legislations Amending Patents Act 1970 :

Chairman :
Hon'ble Shri. I.K. Gujral
Former Prime Minister of India

Members :

Prof. Yashpal
Former Chairman, University Grants Commission

Shri. S.P. Shukla
Former Member, Planning Commission

Prof. Muchkund Dubey
Former Foreign Secretary and currently
Chairman, Council for Social Development

Shri. B.L. Das
Former India's Ambassador to GATT

Prof. Ashok Parthasarathi
Former Secretary to the Government of India and currently
Professor, Centre for Studies in Science Policy
Jawaharlal Nehru University

Prof. Prabhat Patnaik
Prof. of Economics
Jawaharlal Nehru University

Dr. Rajeev Dhavan
Senior Advocate,
Supreme Court of India

Convenor :

Shri. B.K. Keayla
Former Commissioner of Payments and currently
Convenor, National Working Group on Patent Laws.

8. The Commission will be free to decide the procedures and modalities of its work. The Commission may co-opt additional members as, it will also be free to constitute sub-committee to take evidence and hold discussions. The Report of the Commission will be to the people of India, hoping that Parliament and Government of India will consider the views expressed. The Commission is

requested to submit its Report as soon as it deem fit perhaps within a period of 2/3 months. Shri. B.K. Keayla will assist the Commission as the Convenor. The Commission's mailing address will be A-388, Sarita Vihar, New Delhi – 110 044

For and on behalf of the
National Working Group on
Patent Laws

(B.K. Keayla)
Convenor, NWGPL

For and on behalf of the
Public Interest Legal Support and
Research Centre

(Dr. Rajeev Dhavan)
Executive Director, PILSARC

(Prof. Ashok Parthasarthi)
Co-chairman, NWGPL

New Delhi :
February 03, 2004

Comparison of International Prices vis-a-vis Indian Prices: Some Selected Products
Retail Prices in India & wholesale prices in other countries considered
Prices converted into Indian Rs.

Drugs, Dosage & Pack	Prices in India (Rs.)	Prices in Pakistan (Rs.)	Prices in Indonesia (Rs.)	Prices in UK (Rs.)	Prices in USA (Rs.)
Anti infectives					
Ciprofloxacin HCL 500 mg 10's tabs	29.00	423.86	393.00	1185.70	2352.35
Times Costlier		**14.55**	**13.55**	**40.89**	**81.12**
Norfloxacin 400 mg 10's tabs	20.70	168.71	130.63	304.78	1843.66
Times Costlier		**8.15**	**6.31**	**14.72**	**89.06**
Ofloxacin 200 mg 10's tabs	40.00	249.30	204.34	818.30	1973.79
Times Costlier		**6.23**	**5.10**	**20.45**	**49.34**
Cefpodoxime Proxetil 200 mg 6's tabs	114.00	357.32	264.00	773.21	1576.58
Times Costlier		**3.13**	**2.32**	**6.78**	**13.83**
Anti-Ulcerants					
Diclofenac Sodium 50 mg 10's tabs	3.50	84.71	59.75	60.96	674.77
Times Costlier		**24.20**	**17.07**	**17.42**	**192.79**

Comparison of International Prices vis-a-vis Indian Prices: Some Selected Products
Retail Prices in India & wholesale prices in other countries considered
Prices converted into Indian Rs.

Drugs, Dosage & Pack	Prices in India (Rs.)	Prices in Pakistan (Rs.)	Prices in Indonesia (Rs.)	Prices in UK (Rs.)	Prices in USA (Rs.)
Anti-Ulcerants					
Rantidine 150 mg 10's tabs	6.02	74.09	178.35	247.16	863.59
Times Costlier		**12.31**	**29.63**	**41.06**	**143.45**
Omeprazole 30 mg 10's caps	22.50	578.00	290.75	870.91	2047.50
Times Costlier		**25.58**	**12.92**	**38.71**	**91.00**
Lansoprazole 30 mg 10's caps	39.00	684.90	226.15	708.08	1909.64
Times Costlier		**17.56**	**5.80**	**18.16**	**48.97**
Cardiovasculars					
Atenolol 50 mg 10's tabs	7.50	71.82	119.70	NA	753.94
Times Costlier		**9.58**	**15.96**	–	**100.52**
Amlodipine Besylate 5mg 10's tabs	7.80	200.34	78.42	338.28	660.21
Times Costlier		**25.68**	**10.05**	**43.37**	**84.64**

Comparison of International Prices vis-a-vis Indian Prices: Some Selected Products
Retail Prices in India & wholesale prices in other countries considered
Prices converted into Indian Rs.

Drugs, Dosage & Pack	Prices in India (Rs.)	Prices in Pakistan (Rs.)	Prices in Indonesia (Rs.)	Prices in UK (Rs.)	Prices in USA (Rs.)
Anti-Viral Fungal					
Zidovudine 100 mg 10'caps	77.00	313.47	331.65	996.16	895.90
Times Costlier		**4.07**	**4.31**	**12.94**	**11.63**
Lamivudine 150					
Zidovudine 300 mg 10's tabs	274.00	NA	NA	4767.02	4988.62
Times Costlier		–	–	**17.40**	**18.21**
Anti-histamine					
Caterizine 10 mg 10's tabs	6.00	35.71	57.50	262.19	927.29
Times Costlier		**5.95**	**9.58**	**43.70**	**154.55**
Anti-Anxiolotics / Psychotics					
Alpramazoo 0.5 mg 10's tabs	7.00	160.57	31.05	NA	446.81
Times Costlier		**22.94**	**4.43**	–	**63.83**

Comparison of International Prices vis-a-vis Indian Prices: Some Selected Products
Retail Prices in India & wholesale prices in other countries considered
Prices converted into Indian Rs.

Drugs, Dosage & Pack	Prices in India (Rs.)	Prices in Pakistan (Rs.)	Prices in Indonesia (Rs.)	Prices in UK (Rs.)	Prices in USA (Rs.)
Fluoxetine 20 mg 10's caps	25.80	444.53	143.40	395.79	1416.42
Times Costlier		**17.23**	**5.56**	**15.34**	**54.90**
Anti-Cancer					
Boposide 100 mg injection	190.00	554.69	242.90	1217.43	6210.30
Times Costlier		**2.92**	**1.28**	**6.41**	**32.68**
Cholesterol Reducer					
Atorvastatin 10 mg 10's tab	39.00	NA	565.95	537.74	1102.92
Times Costlier		–	**14.51**	**13.79**	**28.28**
Simvastatin 10 mg 10's tabs	35.00	283.05	187.00	537.74	1149.79
Times Costlier		**8.09**	**5.34**	**15.36**	**32.85**

Comparison of International Prices vis-a-vis Indian Prices: Some Selected Products
Retail Prices in India & wholesale prices in other countries considered
Prices converted into Indian Rs.

Drugs, Dosage & Pack	Prices in India (Rs.)	Prices in Pakistan (Rs.)	Prices in Indonesia (Rs.)	Prices in UK (Rs.)	Prices in USA (Rs.)
Antiasthmatic					
Salmeterol 25 mcg Fluticasone 50 mcg inhaler	210.00	NA	782.65	1628.25	NA
Times Costlier		–	**3.73**	**7.75**	–
Urology					
Sildenafil Citrate 50 mg 4's tabs	48.00	NA	1356.93	1614.89	1744.93
Times Costlier		–	**28.26**	**33.64**	**36.35**

Conversion rate of Exchange considered
USD = Rs. 45.50, 1GBP=Rs. 83.51 PAK, Rs. =0.84, 1 Indonesian Rp= Rs. 0.005.
Source for prices : USA Prices - Red Book 2002
UK Prices - UK MIMS Feb. 2004
Pakistan - Pharmaguide June 2002-03
India - IDR Nov/Dec 2003

Annexure -3

Value of Production of Bulk Drugs and Formulations and Export of Drugs and Pharmaceuticals during the years 1994-95 to 2003-04

(Rupees in Crores)

Year	Production		Total Exports
	Bulk Drugs	Formulations	
1994-95	1518	7935	2179.00
1995-96	1822	9125	2337.00
1996-97	2186	10494	4090.00
1997-98	2623	12068	5419.00
1998-99	3148	13878	6152.00
1999-2000	3777	15860	7230.16
2000-2001	4533	18354	8729.89
2001-2002	5439	21104	10475.87
2002-2003*	6529	24185	11925.00
2003-2004*	7779	27692	N.A

* Estimated

Sources : 1. Report of the Working Group on Drugs and Pharmaceuticals For the 9th Five Year Plan Period (1997-1998 to 2001-2002)

2. IDMA Data Bank

3. DGCIS

AIMS AND OBJECTIVES OF PUBLIC INTEREST LEGAL SUPPORT AND RESEARCH CENTRE NEW DELHI, INDIA

- To Develop and initiate legal strategies to serve the needs of public or sections thereof especially the underprivileged.
- To develop social action and public interest litigational strategies to serve society and the public at large and especially the under-privileged.
- To undertake and promote research into social and legal Aspects of dispute settlement in India.
- To initiate and support initiatives for reforms in law consistent with the objectives of promotion of human dignity and just social order.
- To undertake and promote scientific and educational research connected with the administration of law and justice in India and elsewhere.
- To hold discussions, conferences, symposia and seminars.
- To work in co-operation with other kindred societies, institutions and organisations, national and international and to provide for representation in national and international conferences in the pursuit of all or any of the above objects.
- To undertake publications for the purpose of furthering the objects of the centre.
- To liaise with lawyers and legal groups so as to sensitize the legal profession to be more responsible to the needs of the disadvantaged in particular, and the public interest in general.

Aims and Objectives of the National Working Group on Patent Laws New Delhi, India

- To discuss issues relevant and related to the Patent Laws and Paris Convention;
- To discuss issues of national interest arising out of the Uruguay Round of GATT Negotiations;
- To discuss other economics issues raised at various multi-lateral fora having a bearing on the national economy;
- To arrange for research and publication of papers relating to these issues;
- To help create a better understanding of these issues by organising meetings, seminars and debates;
- To press for open discussion/debate in Parliament and other fora so that there is transparency on major economic issues being taken up in multi-lateral negotiations;
- To represent to the Government and those concerned with the formulation of policy on agreed views of the Group;
- Publicise and organise publicity in respect of India's and international patent and other economic laws and policies;
- To forge a National Alliance of various Organisations/ Forum/Associations, etc. to work towards and campaign for patent and other economic laws and policies best suited for India's interests.

Rs. 100 US $ 5